

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF PENNSYLVANIA**

IN RE HEMISPERX BIOPHARMA, INC. LITIGATION	CIVIL ACTION NO.: 09-CV-05262-PD <u>CLASS ACTION</u>
---	---

**CONSOLIDATED CLASS ACTION COMPLAINT  
FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS**

**FILED**

FEB 26 2010

MICHAEL E. KUNZ, Clerk  
By \_\_\_\_\_ Dep. Clerk

## TABLE OF CONTENTS

I.	INTRODUCTION .....	1
II.	NATURE OF THE ACTION .....	2
III.	JURISDICTION AND VENUE .....	6
IV.	THE PARTIES.....	7
	A.    Lead Plaintiff .....	7
	B.    Defendants .....	7
V.	BACKGROUND FACTS.....	8
	A.    The FDA's New Drug Approval Process .....	8
	B.    Timing of FDA Action on a New Drug Application .....	9
	C.    Background Regarding Hemispherx's Ampligen NDA .....	10
	D.    Defendants Bet the Company on the Success of the Ampligen NDA .....	13
	E.    Ampligen Was the Company's Core Product.....	14
VI.	FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD .....	16
	A.    Defendants' November 2, 2009 Revelations .....	31
	B.    Defendants' December 1, 2009 Revelations.....	33
VII.	FACTS WHICH GIVE RISE TO A COGENT INFERENCE OF SCIENTER.....	36
	A.    Defendants Were Motivated to Commit Fraud in Order to Sell More Than \$61.8 Million of Artificially Inflated Securities During the Class Period.....	36
	1.    Defendant Carter Entered into a Standby Financing Agreement that Obligated Him to Personally Finance the Company's Operations if Hemispherx Was Unable to Obtain Other Financing .....	36
	2.    Defendants Were Motivated to Artificially Inflate the Price of Hemispherx Stock to Profit from Class Period Securities Offerings .....	37
	B.    Defendant Carter Tightly Controlled All Hemispherx Communications with the FDA.....	40
	C.    The Company Admits in its SEC Filings That Defendant Carter Was Knowledgeable About the Company's Clinical Trials .....	40
	D.    Defendants Knew That Carcinogenicity Studies and a Third Clinical Trial Were Needed to Prove Safety and Efficacy, But Represented Publicly That They Were Not Needed to Obtain FDA Approval .....	41
	E.    Defendants' Extensive and Frequent Investor Conference Call Discussions Concerning the Ampligen NDA Further Support a Strong Inference of Their Scienter .....	44

F.	Defendants Were Motivated to Commit Fraud in Order to Reward Themselves with Lucrative Bonus Compensation.....	47
G.	A Strong Inference of Defendants' Scienter Is Further Supported by the FDA's Post-Submission Guidelines for Communications with Applicants, Through Which Defendants Learned of or Recklessly Disregarded the Reasons for the Delays of the PDUFA Date and Deficiencies in the NDA .....	48
H.	Defendant Carter's False Explanations of the Delay Further Support a Strong Inference of His Scienter .....	51
I.	A Strong Inference of Scienter Is Further Supported by Defendants' History of FDA Reprimands for Making False Statements About Ampligen .....	52
VIII.	PLAINTIFFS' LOSS WAS PROXIMATELY CAUSED BY THE BELATED DISCLOSURE OF PREVIOUSLY MISREPRESENTED AND OMITTED MATERIAL FACTS .....	55
IX.	APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET .....	61
X.	INAPPLICABILITY OF THE SAFE HARBOR .....	63
XI.	CLASS ACTION ALLEGATIONS .....	63
COUNT I .....	65	
COUNT II.....	66	
PRAYER FOR RELIEF .....	66	
JURY DEMAND .....	67	

**I. INTRODUCTION**

1. Lead Plaintiff the Hemispherx Investor Group, consisting of Victor Cherry, Ehud Nahum, Jagvinder Pal Singh and Padmakar Boienipelly (“Lead Plaintiff”) brings this action individually and on behalf of all persons or entities that purchased and/or acquired the common stock of Hemispherx Biopharma, Inc. (“Hemispherx” or the “Company”) between February 18, 2009 and December 1, 2009 (the “Class Period”) seeking to pursue remedies under the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b) and t(a) (the “Exchange Act”) and Rule 10b-5 promulgated thereunder by the United States Securities and Exchange Commission (“SEC”), 17 C.F.R. § 240.10b-5, against Hemispherx, the Company’s Chief Executive Officer and Chairman of the Board of Directors, William A. Carter, M.D., and the Company’s Medical Director, David R. Strayer, M.D. (collectively, “Defendants”).

2. Lead Plaintiff’s allegations are based upon personal knowledge as to itself and information and belief as to all other matters based upon, among other things: (a) the investigation conducted by and through its attorneys; (b) review and analysis of filings made by Hemispherx with the SEC; (c) review and analysis of press releases, public statements, news articles, securities analysts’ reports and other publications disseminated by or concerning Hemispherx; (d) interview of a former Hemispherx employee, and (e) other publicly available information about Hemispherx. Additional facts supporting the allegations contained herein are known only to the Defendants or are exclusively within their control. Lead Plaintiff believes that substantial additional evidentiary support exists for the allegations set forth in this Consolidated Class Action Complaint (“Complaint”) that will be revealed after a reasonable opportunity for discovery.

**II. NATURE OF THE ACTION**

3. Hemispherx, headquartered in Philadelphia, Pennsylvania, describes itself as a specialty pharmaceutical company engaged in the clinical development, manufacture, marketing and distribution of new drug therapies based on natural immune system enhancing technologies for the treatment of viral and immune based chronic disorders. The Company's core product is Ampligen, an experimental drug undergoing clinical development for the treatment of Chronic Fatigue Syndrome ("CFS"). Other products are Alferon, an antiviral product approved by the U.S. Food & Drug Administration ("FDA") for the treatment of refractory genital warts which the Company was not selling during the Class Period because it chose not to spend its very limited manufacturing funds on it, and Alferon LDO (low dose oral), a product in very early stage development.

4. During the Class Period, Defendants misled investors regarding Hemispherx's New Drug Application ("NDA") for Ampligen which had been initially filed with the U.S. Food and Drug Administration ("FDA") as a treatment for CFS in 2007, on which FDA action was expected in February 2009.

5. Specifically, Defendants disclosed delays in FDA action on the Company's NDA saying explicitly that the delay would be brief and that the FDA did not request additional information at the time of the delays, while concealing deficiencies the FDA had noted previously, of which Defendants were well aware by virtue of the fact that they were then engaged in attempting to respond to them. During the Class Period, Defendants knew that the need to remedy these deficiencies would, at a minimum, delay FDA review and might result in rejection of the application if the FDA could not be satisfied.

6. The market expected that there would be prompt FDA approval of Ampligen to treat CFS, because the Company had no other source of substantial ~~near term~~ revenues, and its financial condition was so poor that, according to SEC filings, it was paying a portion of the salaries and fees of its Board of Directors, employees, consultants and vendors in stock. Therefore, unless it could conduct one or more offerings of its stock, which required market belief that its FDA application would be approved without difficulty or substantial delay, the Company could not pursue its ambitious development plans, or even continue in business for very long.

7. Although the FDA requires statistically significant results using what is called an intent to treat analysis from two controlled trials, and, in the case of a drug used to treat a chronic condition, requires clinical evidence that this drug does not extend the QT interval – a measure of cardiac effect – the Company's NDA did not comply with either of these requirements. Moreover, instead of submitting required rodent carcinogenicity studies, the Company had asked the FDA to waive this requirement. Defendants misrepresented and concealed these facts throughout the Class Period.

8. Further, during its review of the Company's NDA, the FDA requested multiple clinical safety assessments, pre-clinical toxicology reports (including pharmacokinetic studies in multiple animal species), and manufacturing control reports, which were required before the FDA could complete its review or approve the application.

9. In a February 18, 2009 press release and in a May 26, 2009 press release, the Company announced brief delays in FDA action on the Company's NDA, which Defendants attributed to the FDA's workload. On various other occasions during the Class Period,

Defendants made the same misrepresentation, adding that the Company had submitted everything that had been requested.

10. In a March 19, 2009 conference call, Defendant Strayer represented, falsely, that the results for the intent to treat analysis of the treadmill test data from the Ampligen Phase III trial were statistically significant, and that the Company had dispelled FDA concern about Ampligen's effect on QT interval.

11. The truth began to emerge on November 2, 2009, when the Company issued a press release entitled "Hemispherx Biopharma Updates Chronic Fatigue Syndrome (CFS); Treatment and Commercial Application Programs; Targets Completion of All NDA Regulatory Responses and Initiation of Expanded Clinical Collaborations in CFS," which stated in part:

The Company also plans to complete all outstanding queries from the FDA regarding its New Drug Application (NDA) for Ampligen®, an experimental therapeutic, during November and December, 2009. On May 26, 2009, the Company announced a delay on the Ampligen NDA which, at the time, had a PDUFA date of May 25, 2009. As noted in the 10-Q and 10-K filings at the time, the FDA did not request additional information from the Company at that time. *However, several outstanding NDA items, requiring Hemispherx responses, existed at the time of the FDA delay as noted in the August 8, 2009, 10-Q filing. Between March 9, 2009 and September 15, 2009, the Company issued six (6) new reports to the Agency spanning various subjects including a) clinical safety assessments, b) specialized pre-clinical toxicology reports, and c) abbreviated chemistry and manufacturing control reports.* The Company believes that these reports may fully retire all agency queries in these particular areas.

*The company also plans to submit four (4) additional reports on interrelated topics in November and December, 2009, which will include pharmacokinetic analyses in multiple lower animal species (primates, rodents, etc.) ("the Lovelace Laboratory Studies") and final validation reports of certain manufacturing procedures conducted at an independent facility, Hollister-Stier Laboratories in Spokane, WA.* Some of these reports were recently cited in BioMedReports.com and the Science Business Exchange (October 15, 2009).<sup>1</sup>

---

<sup>1</sup> Emphasis added unless otherwise noted.

12. As a result of the November 2, 2009 disclosure, the price of Hemispherx common stock plummeted from \$1.45 per share on October 30, 2009, to close at \$1.33 per share on November 2, 2009 (an 8.28% decline) on unusually heavy volume of 2,409,294 shares traded; and to decline further on November 3, 2009, when it closed at \$1.13 per share (a 15.04% decline), on unusually heavy volume of 8,739,506 shares traded. This decrease was the result of Defendants' disclosure of facts that had previously been concealed and caused the price of the Company's common stock to be artificially inflated.

13. On December 1, 2009, after the market closed, the Company issued a press release which disclosed that the FDA advised the Company in a complete response letter that the NDA for Ampligen could not be approved because, among other things, the clinical (human) studies submitted with the application "*did not provide evidence of efficacy of Ampligen*," a finding which was substantially based on the fact that the results for the intent to treat analysis of the primary endpoint of the Phase III trial were not statistically significant. The December 1, 2009 press release disclosed that as a result, the Company could not hope to obtain approval of Ampligen without conducting at least one additional large human study "which shows a convincing effect and confirms safety in the target population" – mentioning the need for evidence of cardiac safety. *Further, the December 1, 2009 press release admitted that the FDA is recommending that the Company complete rodent carcinogenicity studies in two species, which the Company had chosen not to perform, but instead asked the FDA to waive.*

14. As a result of the foregoing disclosures in the December 1, 2009 press release, the market price of Hemispherx common stock plunged an additional \$0.49 per share, from a closing price of \$1.20 per share on December 1, 2009 to close at \$0.71 per share on December 2, 2009, a decline of 40.83%, on unusually heavy volume of 26,168,813 shares traded; and to decline

further on December 3, 2009, when it closed at \$0.68 per share (a 4.23% decline), on unusually heavy volume of 7,510,378 shares traded.

**III. JURISDICTION AND VENUE**

15. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. §§ 1331.

16. The claims alleged herein arise under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated under Section 10(b) (17 C.F.R. § 240.10b-5).

17. Venue is proper in this District pursuant to Section 27 of the Exchange Act, and 28 U.S.C. § 1331(b) and (c). Substantial acts in furtherance of the alleged fraud and/or its effects, including the preparation and dissemination to the investing public of materially false and misleading reports, occurred in this District. Additionally, Hemispherx maintains its principal executive office in this Judicial District.

18. In connection with the acts, omissions and other wrongs complained of herein, the Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the United States mail, interstate telephone communications, and the facilities of the national securities markets.

**IV. THE PARTIES**

**A. Lead Plaintiff**

19. Lead Plaintiff, as set forth in the Certifications previously filed with the Court and incorporated herein by reference, purchased the publicly traded common stock of Hemispherx at artificially inflated prices during the Class Period, and has suffered damages as a result of the disclosure of the wrongful acts of Defendants, as alleged herein.

**B. Defendants**

20. Defendant Hemispherx is a biopharmaceutical company that maintains its principal executive offices at One Penn Center, 1617 JFK Boulevard, Philadelphia, Pennsylvania. The Company was founded in 1966 under the name HEM Research, Inc., and went public in November 1995, raising \$16 million in its initial public offering. At all times relevant to this action, Hemispherx common stock has been listed for quotation on the NYSE Amex exchange.

21. Defendant William A. Carter, M.D. ("Carter") has been Chairman of the Board of Directors since January 1992 and Chief Executive Officer ("CEO") since July 1993. Defendant Carter has also served as Hemispherx's Chief Scientific Officer since May 1989, President since April, 1995, and as a director since 1987. Defendant Carter is the co-inventor of Ampligen and joined Hemispherx in 1978. Defendant Carter reviewed, approved and signed certain of Hemispherx's false and misleading SEC filings during the Class Period and made false and misleading statements during the Company's Class Period investor conference calls.

22. Defendant David R. Strayer, M.D. ("Strayer") has served as Medical Director of the Company since 1986. Defendant Strayer made false and misleading statements during certain of the Company's Class Period investor conference calls.

**V. BACKGROUND FACTS**

**A. The FDA's New Drug Approval Process**

23. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§301-97, new pharmaceutical products cannot be marketed or sold in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. §§355(a) & (d). The steps required before a drug may be marketed in the U.S. include: (i) preclinical laboratory and animal tests; (ii) submission to the FDA of an application for an Investigational New Drug ("IND") exemption, which must become effective before human clinical trials commence; (iii) human clinical trials to establish the safety and efficacy of the drug, typically proceeding in three phases; (iv) submission of a detailed NDA or Product or Biologics License Application ("BLA") to the FDA; and (v) FDA approval of the NDA/BLA. The FDA does not approve a drug for treatment of a disease in general. Instead, a drug is approved for treatment of a specific condition, or "indication," for which the drug has been tested in patients. For each approved indication, the FDA will specify particular dosages and dosage frequency determined to be safe and effective.

24. In addition, the FDA approves particular rather than general claims of efficacy, which limits the claims that the seller of the drug can make in its advertising and promotional material. For example, with respect to CFS, Hemispherx applied for FDA approval of Ampligen as a treatment for CFS, limited to the claim that the drug increases exercise duration, as demonstrated by increased mean treadmill exercise duration for CFS patients, because that was the primary endpoint of the only Phase III clinical trial of Ampligen in the treatment of CFS patients that was conducted by the Company. Even if the NDA was approved, the Company would not be able to make other claims without running afoul of the Food, Drug & Cosmetic Act, because they would not have been proven in clinical trials.

25. Success or failure of a clinical trial is determined by the ability of the trial to meet its endpoints, including a demonstration that the results are statistically significant. “Statistically significant” means that a given result is unlikely to have occurred by random chance, or due to factors outside of the control of the study. Statistical significance is measured on a scale of zero (0) to one (1). A statistical significance level of 0.05 (5%) is the traditional scientific standard for determining whether given results are statistically significant. A result is expressed as a “p-value,” which is a statistical measure of the probability that a difference between groups in a clinical trial happened by chance. Statistical significance consisting of a p-value of less than 0.05 has traditionally been considered convincing evidence of efficacy by the FDA. A p-value of 0.05 means that there is a one in forty likelihood that the result occurred by chance. The lower the p-value, the more likely it is that the difference between an experimental group and a control group was caused by the drug, rather than by chance.

**B. Timing of FDA Action on a New Drug Application**

26. The Prescription Drug User Fee Act (“PDUFA”), enacted in 1992 and amended in 1997 and 2002, authorizes the FDA to collect substantial “user fees” from pharmaceutical and biotechnology companies at the time an NDA is submitted, with those funds designated for use only in Center for Drug Evaluation and Research (“CDER”) or Center for Biologics Evaluation and Research (“CBER”) drug approval activities. In order to continue collecting such fees, the FDA is required to meet certain performance benchmarks, primarily related to the speed of certain activities within the NDA review process.

27. The so-called “PDUFA clock” starts on the day the NDA is filed with the FDA. The FDA has up to six months – and generally takes it – to issue an approval decision. Drug and biotech firms typically issue press releases when they file an NDA so that investors can calculate the date by which the FDA must issue its decision, often referred to as the “PDUFA date.”

**C. Background Regarding Hemispherx's Ampligen NDA**

28. Ampligen is an investigational drug that is experimental in nature and is available legally only through clinical trials. At all times relevant to this action, Ampligen was undergoing clinical development for the treatment of CFS.

29. Ampligen was co-invented by Defendant Carter in the 1970s and was licensed to Hemispherx. Since that time, Ampligen has been a drug in search of a disease.

30. Hemispherx has sought FDA marketing approval for Ampligen for approximately two decades. At various times, Hemispherx has promoted and engaged in early testing of Ampligen as a treatment for chronic hepatitis B, smallpox, HIV, Ebola, avian flu, and most recently the H1N1 virus. However, virtually all of the Company's efforts and funds have been spent on CFS.

31. In October 1987, Du Pont entered into a partnership with Hemispherx, to develop Ampligen in the treatment of AIDS. Expecting Ampligen to be a high flier, Du Pont acquired 6% of HEM's stock for \$10 million and agreed to fund part of a 300-person clinical trial, according to reports. After Ampligen flunked the clinical trial of its effectiveness in treating AIDS, Du Pont terminated its partnership with Hemispherx in October 1988. It was around the same time that Hemispherx fired Defendant Carter (then the Company's CEO) for mismanagement of the AIDS clinical trials. The Company switched its attention to CFS, a poorly understood syndrome with no known cause that starts with flu-like symptoms and progresses to chronic weakness and fatigue.

32. There is no laboratory test or barometer for CFS, which is diagnosed by observing a set of symptoms consistent with CFS, and ruling out all other known causes for the symptoms. As defined by the U.S. Centers for Disease Control & Prevention, to receive a diagnosis of CFS, a patient must satisfy two criteria:

- a. Experience severe chronic fatigue of six months or longer duration with other known medical conditions excluded by clinical diagnosis; and
- b. Concurrently exhibit four or more of the following symptoms: substantial impairment in short-term memory or concentration; sore throat; tender lymph nodes; muscle pain; multi-joint pain without swelling or redness; headaches of a new type, pattern or severity; unrefreshing sleep; and post-exertional malaise lasting more than 24 hours.

33. In addition to the eight primary defining symptoms of CFS, a number of other symptoms have been reported by 20% to 50% of CFS patients. These symptoms include abdominal pain, alcohol intolerance, bloating, chest pain, chronic cough, diarrhea, dizziness, dry eyes or mouth, earaches, irregular heartbeat, jaw pain, morning stiffness, nausea, and night sweats.

34. By 1990, Defendant Carter found his way back in the Company. Under Defendant Carter's leadership, the Company filed an application for a "treatment IND" for Ampligen on September 3, 1991, based on the results of a study involving 92 patients with CFS. A "treatment IND" status is intended to provide desperately ill patients with experimental drugs even before they are approved for marketing. Treatment IND status is given to drugs completing Phase II or currently in Phase III trials.

35. In October 1991, the FDA notified the Company that its application to provide Ampligen under a treatment IND for patients with chronic fatigue syndrome was placed on hold as the data did not support the expansion of Ampligen treatment. In its letter, the FDA stated that Hemispherx's study results involving 92 patients were preliminary and that data submitted to the FDA were incomplete and inadequate to assess safety and effectiveness of the drug in

CFS. The FDA had also raised serious concerns about the potentially life-threatening reactions including acute liver toxicity, severe abdominal pain and irregular heartbeat that were observed during the study. The following year, in October 1992, Hemispherx was authorized by the FDA to begin a Phase II study of Ampligen for the treatment of CFS.

36. In 1994, the results of the Phase II study of Ampligen in CFS were published. The study enrolled 92 CFS patients (45 randomized to Ampligen and 47 assigned to a placebo) and treated them for 24 weeks. According to the Company, in the study, patients treated with Ampligen reported a "clinically significant" improvement in their functional impairment (primary endpoint of the study) compared to placebo, as measured by the Karnofsky Performance Scale, a scale which measures functional performance. Based on this study, Hemispherx pushed Ampligen into a larger, Phase III study.

37. The Phase III clinical trial ("AMP 516") began enrolling patients in 1998. The study used the same dose of Ampligen as the Phase II study, but extended the treatment to 40 weeks and changed the primary endpoint to improvement in treadmill exercise tolerance testing. On May 3, 2006, Hemispherx issued a press release announcing that the Company was presenting the "audited results" of its Phase III study that day at the 5th International Conference on HHV [human herpes virus] in Barcelona, Spain. According to the May 3, 2006 press release, "[t]he presentation shows that the tests achieved improvements far above the levels considered medically significant." The May 3 press release also states:

... In the recently completed Phase III trial, patients receiving Ampligen (R) for 40 weeks improved exercise treadmill performance by 14.8% compared to the placebo group, and 12.9% by intent to treat analysis. That's twice the minimum level considered to be medically significant, which is 6.5%."

However, the statistical result improved treadmill performance using the intent to treat analysis, which is the analysis that the FDA considers the relevant analysis because it counts the results for all of the patients in the trial, **was not statistically**

**significant.** As the research abstract presented at the May 3, 2006 medical conference in Barcelona revealed, the statistical p-value for the intent to treat analysis in the Phase III trial was  $p=0.052$ , which is higher than  $p=0.05$ , and, as a result, is **not** statistically significant. Therefore, that result did not meet FDA statistical standards.

38. Hemispherx initially filed an NDA for Ampligen with the FDA for treatment of CFS on October 10, 2007. On December 5, 2007 Hemispherx received a Refusal to File letter from the FDA because its NDA filing was deemed "not substantially complete." Hemispherx filed amendments to its Ampligen NDA on April 25, 2008. On July 7, 2008, the FDA accepted for review Hemispherx's NDA for Ampligen as a treatment for CFS. The Company claims that Ampligen is the first drug in the class of RNA (nucleic acid) molecules to apply for NDA review.

39. According to Defendants, a response from the FDA was expected by February 25, 2009. On December 1, 2009, after reporting several delays which Defendants represented were not due to any deficiencies in the NDA, the Company announced that the FDA had rejected the application and that the Company would need to conduct a new large human trial and several animal studies in support of an amended NDA.

**D. Defendants Bet the Company on the Success of the Ampligen NDA**

40. At all times relevant to the Class Period, Defendants essentially bet the Company on the Ampligen NDA. As a result of the Company's decades long pursuit of FDA approval of Ampligen, Hemispherx was a company in desperate need of cash. According to the Company's Form 10-K filed with the SEC on March 9, 2009, Hemispherx reported net income only from 1985 through 1987. Since 1987, Hemispherx has incurred substantial operating losses due to its research and development programs. The only commercial product of Hemispherx is Alferon Injection, approved solely for the treatment of refractory genital warts, and sold in the U.S., Mexico, Germany, Singapore, and Hong Kong.

41. The Company derives its revenue only from the Ampligen cost recovery program and commercial sales of Alferon Injection. As reported in Hemispherx's Form 10-Q for the quarter ended March 31, 2009, the Company had "not yet generated significant revenues from [its] products," and as of March 31, 2009, had an accumulated deficit of more than \$200 million. By September 30, 2009, Hemispherx's accumulated deficit had increased to more than \$206 million.

42. In recent years, the costs for development of Ampligen have consumed most of the Company's resources and represented its largest investment. For example, the March 9, 2009 Form 10-K states:

Cash used in operating activities for the year ended December 31, 2008 was \$9,358,000 *reflecting mainly expenditures for the preparation and filing of the Ampligen(R) NDA....* As of February 28, 2009 we had approximately \$5,734,000 in cash and cash equivalents and short-term investments, or a decrease of approximately 6.3% from December 31, 2008.

Given the harsh economic conditions, *we have reviewed every aspect of our operations for cost and spending reductions to assure the long-term survival of our Company while maintaining the resources necessary to achieve our primary objectives of obtaining NDA approval of Ampligen(R) and securing a strategic partner.* We believe, but cannot assure, that our current funds should be sufficient to meet our operating cash requirements for the next 16 months as we have taken the steps discussed below to curtail discretionary spending to conserve cash and reduce our monthly burn rate.

#### **E. Ampligen Was the Company's Core Product**

43. Defendants admit in the Company's Class Period SEC filings that Ampligen was the Company's core product and the Ampligen NDA was Hemispherx's most important project. For example, Defendants disclosed in the Company's Form 10-Q for the quarter ended September 30, 2009 filed with the SEC on November 9, 2009, that Ampligen represents one of the Company's "two core pharmaceutical platforms":

Our current strategic focus is derived from four applications of *our two core pharmaceutical technology platforms Ampligen® and Alferon N Injection®.*

The commercial focus for Ampligen® includes application as a treatment for Chronic Fatiguc Syndromc ("CFS") and as a vaccine enhancer (adjuvant) for both therapeutic and preventative vaccine development. Alferon N Injection® is a Food and Drug Administration ("FDA") approved product with an indication for refractory or recurring genital warts. Alferon® LDO (Low Dose Oral) is an application currently under early stage development targeting influenza and viral diseases both as an adjuvant as well as a single entity anti-viral.

44. Moreover, Defendants have looked to Ampligen as the drug that would lead the Company to profitability. Indeed, at all times relevant to this action, Defendants emphasized the commercial potential for Ampligen as a blockbuster drug (a drug with sales in excess of a billion dollars), based on the following:

- a. During the Class Period, no drug therapy for CFS had received U.S. marketing approval. Indeed, to date, no CFS drug has reached the market.
- b. If approved by the FDA, Ampligen would be the only drug therapy for treatment of CFS.
- c. Hemispherx is the only manufacturer of Ampligen in the world.
- d. If Ampligen received FDA approval, Hemispherx would have been the exclusive manufacturer of the only CFS drug therapy.

45. Defendant Carter stated in the March 19, 2009 conference call that the potential market for Ampligen is \$1 billion: "A drug in this class would certainly have the potential to be a \$1 billion product assuming that it was accepted in the marketplace...."

46. Defendant Carter suggested during the March 19, 2009 conference call that there are upwards of a million patients who would potentially take Ampligen and that the Company could expect reimbursements of \$16,000 to \$20,000 per year for each patient:

**William Carter - Hemispherx Biopharma, Inc. - Chairman, CEO**

As you know, there are between 4 million and 6 million Americans who have the

**Unidentified Participant**  
Chronic syndrome.

**William Carter - Hemispherx Biopharma, Inc. - Chairman, CEO**

the disorder, and let's say 25% of them, more or less, are very, very ill. These would be the first patients who might qualify when and if the drug is approved. Under the emergency regulations, we presently provide the drug on a cost reimbursement basis for \$16,000 to \$20,000 a year. So obviously, there would probably be a step-up in that pricing if the product receives a full approval. But in essence, you can run the numbers yourself. As you know, there are no other products on the market that are approved.

**VI. FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD**

47. On February 18, 2009, the Company issued a press release entitled "FDA Extends Hemispherx's NDA Review Date for Ampligen® as Potential Treatment for CFS," which revealed that, due to the agency's workload, there would be a three-month delay in FDA action on the Company's application for approval of Ampligen as a treatment for CFS. The February 18 press release stated:

Hemispherx ... has received a letter from the Food and Drug Agency ("FDA") indicating that the originally scheduled Prescription Drug User Fee Act ("PDUFA") date on the Ampligen® (Poly I:Poly C12U) New Drug Application (NDA) would be extended by three months "in order to provide time for a full review of the submission." Additional data were received by the FDA within 3 months of the user fee goal date.

*Due to constraints at the FDA, specifically and including the increased workload related to the recently enacted and implemented FDA Amendments Act ("FDAAA") and FDA's Safety First/Safe Use initiatives, work priorities may change resulting in the Agency going past the customary PDUFA goal set for reviews of an application.*

A decision was originally expected by February 25, 2009, for the Company's submission of its Ampligen® NDA, which is designated as an Orphan Drug for the treatment of Chronic Fatigue Syndrome, which has no FDA approved treatments on the market. Ampligen® is also authorized for Emergency (compassionate) Cost Recovery Sales Authorization by the FDA and has a "promising" designation by the Agency on Health Research Quality (AHRQ): "Ampligen®, an investigational drug that is not approved by the FDA, given intravenously to severely debilitated patients, yielded the most promising results." The extended user fee goal date is now May 25th, 2009.

Extensions of NDA reviews are a separate category of FDA response, distinct from a complete response letter or approval by the PDUFA date, and have always existed. Prior to the recent new FDA initiatives (cited above) and resultant increased workload, “on time” action by the Agency has generally ranged between 68 and 100 percent for the standard NDA reviews between FY 1999 and FY 2006 (source: Annual FDA PDUFA Performance Reports ([www.FDA.gov](http://www.FDA.gov))).

48. Defendants’ statements in the February 18, 2009 press release were materially false and misleading because Defendants knew or recklessly disregarded that the FDA could not have completed its review of the Ampligen NDA by February 25 regardless of any issues relating to “increased workload related to the recently enacted and implemented FDA Amendments Act ... and FDA’s Safety First/Safe Use initiatives.” As Defendants later admitted, at the time they made the false and misleading February 18 representations, they were in the process of responding to FDA requests for a wide variety of reports, which the Company needed to submit before the FDA would complete its review, including clinical safety assessments, specialized pre-clinical toxicology reports, and chemistry and manufacturing control reports. As Defendants admitted in Hemispherx’s November 2, 2009 press release and the November 9, 2009 Third Quarter Form 10-Q:

**Between March 9, 2009 and September 15, 2009, we issued six new reports to the FDA spanning various subjects including clinical safety assessments, specialized pre-clinical toxicology reports and abbreviated chemistry and manufacturing control reports. We also plan to submit four additional reports on interrelated topics in November and December 2009, which will include pharmacokinetic analyses in multiple lower animal species (primates, rodents, etc.) regarding the Lovelace Respiratory Research Institute studies and final validation reports of certain manufacturing procedures conducted at an independent facility, Hollister-Stier Laboratories in Spokane, WA.**

November 9, 2009 Form 10-Q.

49. On March 13, 2009, the Company filed its 2008 Annual Report on Form 10-K with the SEC for the year ending December 31, 2008, which was signed by Defendant Carter, and stated in part:

On July 7, 2008 we were notified that the FDA had accepted for review our amended NDA filing for using Ampligen® to treat CFS. FDA approval of this application would provide the first-ever treatment for CFS. As present, only supportive symptom-based care is available for CFS patients.

\* \* \*

#### FDA Extends NDA Review Date for Ampligen®

In February 2009, the Company received a letter from the Federal Drug Administration (“FDA”) indicating that their originally scheduled Prescription Drug User Fee Act (“PDUFA”) date on the Ampligen® (Poly I:Poly C12U) New Drug Application (“NDA”) would be extended by three months “in order to provide time for a full review of the submission.” A decision from the FDA was originally expected by February 25, 2009. The extended PDUFA date for Ampligen® is now scheduled for May 25, 2009. *Due to constraints at the FDA, specifically and including the increased workload related to the recently enacted and implemented FDA Amendments Act and Safety First/Safe Use initiatives, work priorities may change resulting in the agency going past the customary PDUFA goal date set for reviews of an NDA.*

Extensions of NDA reviews are a separate category of FDA response, distinct from a complete response letter or approval by the PDUFA date, and have always existed. Prior to the recent new FDA initiatives (cited above) and resultant increased workload, “on time” action by the agency has generally ranged between 68 and 100 percent for the standard NDA reviews between fiscal years 1999 and 2006 (source: Annual FDA PDUFA Performance Reports ([www.FDA.gov](http://www.FDA.gov))).

50. Defendants' statements in the March 13, 2009 Form 10-K were materially false and misleading in their attributions of the delayed PDUFA date to FDA “constraints” and “increased workload” for the same reasons as the February 18, 2009 press release.

51. At the IACFS/ME 9th International Research and Clinical conference from March 12-15, 2009 in Reno, Nevada, Defendant Strayer made a presentation regarding Ampligen, in which he reported that there were no safety concerns from treatment with Ampligen and that patients were able to decrease use of other medications while taking Ampligen:

Interferon and cytokine levels in the phase III trial of Poly I: Poly C12U (ampligen) was presented by David Strayer (Philadelphia, USA). Pre-treatment and intra-patient changes from baseline were compared to see if the treatment had a significant effect on serum levels. Patients had improved significantly in treadmill tests and decreased use of other medications with this treatment, but

there was no significant modulation of interferons or cytokines. No safety concerns were raised and the treatment was well tolerated. The decrease in use of concomitant medications was an important point, as several of the medications used regularly in CFS do cause prolongation of the QT interval, with possible risk of death. Overall death rates in CFS patients due to heart failure, suicide and cancer were reduced.

52. On March 19, 2009, during the Company's fourth quarter 2008 earnings conference call with securities analysts and investors, defendant Carter made the following statements:

**William Carter - *Hemispherx Biopharma, Inc. - Chairman, CEO***

**We believe that we have answered all the major questions that have been put forward with the Agency.** Now under federal law, they can continue to ask questions as long as they want.

**But we believe that the major questions which they have asked have in our opinion been retired.** Obviously, we are trying to anticipate questions that might come up in the future so that we can be prepared should there be further questions.

**Unidentified Participant**

That is May 25 that is going to come up?

**William Carter - *Hemispherx Biopharma, Inc. - Chairman, CEO***

**Yes, May 25, we would expect definitive response letters at that point.**

53. Defendant Carter's statements during the March 19, 2009 conference call were materially false and misleading because he knew that the Company had not "answered all the major questions" from the FDA. On the contrary, the Company was then responding to numerous FDA requests for additional information concerning the Ampligen NDA. As Defendants admitted in the November 2, 2009 press release, at the time of the March 19, 2009 conference call, the Company was compiling and submitting new reports to the FDA on a variety of topics, including clinical safety assessments, specialized preclinical toxicology reports and

chemistry and manufacturing control reports. In fact, the Company continued to respond to these outstanding FDA requests until and after the end of the Class Period.

54. In the March 19, 2009 conference call, Defendant Carter discussed what he called one of the “overarching challenges in pharmaceutical research,” “a challenge to all drugs that are potentially given on a chronic basis,” which he referred to as “the Vioxx problem.” (Vioxx was the Merck arthritis drug that the FDA caused to be withdrawn from the market when it caused serious, even fatal, cardiac effects.) Defendant Carter called this problem “the unintended cardiovascular consequences of drugs given to the chronically disabled population.”

55. In the March 19, 2009 conference call, addressing the issue of the possible cardiotoxicity of Ampligen, Defendant Strayer said that:

The QT interval is a part of the EKG complex, and the importance of it is that when this interval gets prolonged, it increases the risk of arrhythmias and of sudden death.

\* \* \*

So what we did is we looked – again in the 516 study we looked we looked at the QT interval in the Ampligen group versus the placebo group. We actually found that the placebo group had a prolonged QT interval compared to the Ampligen group. We began to probe this. We found that it was directly related to the number of medications they were taking that prolong the QT interval.

This was true in both AMP 502, our first randomized placebo-controlled study, as well as the second one, AMP 516.

So these results really from two independent clinical trials suggest that the therapeutic benefit of Ampligen allows patients to reduce their dependence on concomitant medications used to treat the symptoms of CSF, and thereby specifically reducing exposure to these drugs that are known to prolong the QT interval. So we think this is a very important finding, and we have recently submitted this data to the Agency.

56. In the March 19, 2009 conference call, Defendant Strayer also represented, in response to a question by a securities analyst, that the results for the intent to treat analysis of the treadmill time, the primary endpoint of Phase III Ampligen trial, "are statistically significant."

57. Defendants Strayer's and Carter's statements about cardiotoxicity were materially misleading by reason of the failure to disclose the fact that in the Phase III trial, patients treated with Ampligen experienced arrhythmia, a cardiac effect, and the Company had not performed the FDA prescribed testing to determine the effect of a drug for a chronic condition on QT interval, as described in Guidance for Industry: Clinical Evaluation of QT/QTC Interval Prolongation and Proarrhythmia Potential for Non-Antiarrhythmic Drugs. As a result, as the Company announced in a December 1, 2009 press release, the FDA required the Company to perform a "well-controlled QT interval study" as one of the prerequisites to approval of Ampligen as a treatment for CFS.

58. Defendant Strayer's representation that the result for the intent to treat analysis for the primary endpoint of the Phase III trial was statistically significant was false, as the p-value for that result was  $p=0.052$ , which is greater than  $p=0.05$ , and, therefore, not statistically significant. Results that are not statistically significant are not normally considered credible evidence by the FDA. Indeed, in a December 1, 2009 press release, Hemispherx disclosed that "the FDA stated that the two primary clinical studies submitted with the NDA did not provide credible evidence of efficacy of Ampligen."

59. Also during the March 19, 2009 conference call, Defendant Carter asked Defendant Strayer to report to investors about new cardiovascular data. As shown below, Defendants claimed that this new data supported safety of Ampligen by blaming certain adverse

cardiac effects, known as prolonged QT interval, on other medications certain study patients were taking:

**William Carter - *Hemispherx Biopharma, Inc. - Chairman, CEO***

Okay. Tell us a little bit about the new cardiovascular (multiple speakers) data.

**David Strayer - *Hemispherx Biopharma, Inc. - Medical Director - Regulatory Affairs***

Yes, we have shown in previous publications and presentations that the **Ampligen patients actually can reduce the use of concomitant medications that they take to relieve the symptoms of CSF....** CSF patients utilize numerous medications to try to ameliorate their symptoms.

We now wanted to look at a specific class of these drugs that they take to see whether or not we could show that this particular very important class that has cardio toxic effects actually was reduced as well. This class are drugs that prolong the QT interval. The QT interval is part of the EKG complex. And the importance of it is that when this interval gets prolonged, it increases the risk of arrhythmias and of sudden death.

So what we did is we looked – again in the 516 study we looked at the QT interval in the Ampligen group versus the placebo group. **We actually found that the placebo group had a prolonged QT interval compared to the Ampligen group.** We began to probe this. We found that it was directly related to the **number of medications they were taking that prolong the QT interval.**

This was true in both AMP 502, our first randomized placebo-controlled study, as well as the second one, AMP 516.

**So these results really from two independent clinical trials suggest that the therapeutic benefit of Ampligen allows patients to reduce their dependence on concomitant medications used to treat the symptoms of CSF, and thereby specifically reducing exposure to these drugs that are known to prolong the QT interval.** So we think this is a very important finding, and we have recently submitted this data to the Agency.

60. These statements falsely assured investors that Hemispherx had performed adequate cardiac safety studies and that any prolonged QT interval problems were not caused by Ampligen but instead were due to other medications. In this way, Defendants conditioned the

market to believe that the FDA would not require the Company to perform additional cardiac safety studies. However, the fact that the Company was submitting this QT interval data reveals that the FDA was making inquiries regarding the cardiac safety of Ampligen and, as Defendants admitted in the December 1, 2009 press release, not only did the FDA require the Company to perform a third clinical trial, but the FDA also required that this study include a well-controlled QT interval study.

61. On May 11, 2009, the Company issued a press release entitled "Hemispherx Biopharma Announces \$18.3 Million Public Equity Offerings," which stated in part:

Hemispherx Biopharma announced today that it has agreed to sell up to \$18.3 million in common stock and warrants in a registered offering to two institutional investors. The investors will purchase today, for \$15 million cash, common shares of its stock at \$1.10 per share.

62. Also on May 11, 2009, the Company filed its Form 10-Q with the SEC for the quarter ended March 31, 2009, which stated in part:

On July 7, 2008, the FDA accepted for review our NDA for Ampligen® to treat CFS, originally submitted in October 2007. We are seeking marketing approval for the first-ever treatment for CFS. At present, only supportive, symptom-based care is available for CFS patients.... On February 18, 2009, we were notified by the FDA that the originally scheduled Prescription Drug User Fee Act date of February 25, 2009 has been extended to May 25, 2009.

63. On May 19, 2009, the Company revealed in a press release issued on that date that it had again reaped the fruits of its misrepresentations about the delayed FDA action on its application for approval for Ampligen as a treatment for CFS, announcing that institutional investors purchased Hemispherx stock for \$16 million, stating:

Hemispherx Biopharma announced today that it has agreed to sell up to \$16 million in common stock and warrants in a registered offering to two institutional investors. The investors will purchase for \$16 million cash, 11,906,976 common shares of its stock at \$1.34375 per share.

64. As a result of stock and warrants issued in the offerings announced on May 11 and 19, the Company raised approximately \$33,712,000.

65. On May 26, 2009, the Company issued a press release announcing yet another delay in FDA action, again blamed on FDA scheduling issues and denied that the FDA had requested additional information, entitled "Hemispherx Biopharma Announces Possible Brief Delay in FDA Action on Ampligen® New Drug Application," which stated:

Hemispherx Biopharma, Inc. today announces that the U.S. Food and Drug Administration ("FDA") has advised the Company that it may require up to 1-2 additional weeks to take action beyond the scheduled Prescription Drug User Fee Act action date of May 25, 2009 on the New Drug Application for Ampligen® (Poly I:Poly C12U), a selective TLR3 modulator, for the management of Chronic Fatigue Syndrome. Reason for the possible delay was attributed by the Agency to certain staff scheduling changes which might (or might not) delay the report. Accordingly the Company's development plan for Ampligen® continues as described in the recently filed 10Q and 10K, as the FDA did not request additional information from the Company at this time.

This statement was materially false and misleading for the same reasons as the February 18, 2009 press release.

66. On June 12, 2009, during a *biomedreports.com* interview, defendant Carter made the following statements:

**Interviewer:** First of all, let's talk about what everyone is talking about, which is the FDA decision, is it safe to say that we haven't heard anything from the FDA in regards to Ampligen?

**Dr. Carter:** Correct.

67. Defendant Carter's statement at the June 12, 2009 interview was materially false and misleading when made because he knew, but intentionally concealed, that the FDA had been in contact with Hemispherx and made multiple inquiries regarding the Ampligen NDA, and Hemispherx was actively engaged in responding to these inquiries throughout the Class Period. As Defendants admitted in the Company's November 2, 2009 press release, at the time of the

June 12, 2009 interview, the Company was compiling and submitting new reports to the FDA on a variety of topics, including clinical safety assessments, specialized preclinical toxicology reports and chemistry and manufacturing control reports, specifically in response to FDA inquiries relating to the FDA. In fact, the Company continued to respond to outstanding FDA requests throughout the Class Period and thereafter.

68. On July 22, 2009, on the Company's conference call with investors and analysts, Defendant Carter made the following statements:

Mr. Welsh: Yes, I was wondering if there's any foreshadowing or new news of the FDA's approval of Ampligen?

Dr. Carter: ... I gave a brief status report at the introduction to this conference call. We have not received any recent news from the agency. And as I pointed out earlier in a call, we have a number of initiatives in the CFS area which are not dependent upon that specific – that specific set of correspondences from the agency.

And so we're moving on these – we're moving on a whole series of initiatives with respect to clinical trials, market development, safety study reports.

In the past, we've issued some re-reports. Now we're issuing complete audited reports on a variety of safety issues that the agency has raised over several years; no – no new issues, but now we're retiring them through – we believe we're retiring them through more comprehensive reporting. So this is all – this is all going forward.

**And as you know from earlier conference calls, we believe the agency is substantially overworked at the moment with its new initiatives. It has new senior management.** And we expect that sometime in the fall, perhaps sooner, we will be hearing from the – from the agency.

\* \* \*

[Carter]: What we – what we're doing now, since since we believe that we've received the totality of significant questions and have retired them, we're now creating the dossier for Canada and for selected European countries.

\* \* \*

Steve Gold: Hi Good Morning. The last we heard – well, we heard from the FDA – there was a one- or two-week delay, and I heard you discuss the FDA earlier, at the beginning of the call. I want to get a little bit specific about that, if I

may. That was about two – two months ago or so. Next, we heard you say that you're expecting – now you're expecting a response sometime in the fall. What do you attribute this tremendous delay to? And to say that the agency is overworked or overloaded, wouldn't it be reasonable for the company to request an update – an updated timeline from the FDA?

\* \* \*

[Carter]: So this is a – this is a – this is a common phenomenon with respect to the agency. And even though it is hiring several thousand new people under its recent congressional appropriation, it's going to take awhile to train them.

I don't – I don't want to suggest – and if I suggested it, that we are not in – we are not in correspondence with the agency, that would be correct. We are regularly providing reports to the agency to different reviewers and different areas; for example, in the area of preclinical toxicology. And so we are in correspondence.

With respect to the question of – the definitive answer to our pending NDA, it's been our impression and that of – and that of our regulatory counsel that the agency knows that we are most eager to – to determine what their deliberations are. They were present at a meeting at the end of May as a member of the HHS committee.

\* \* \*

[Carter]: And we feel that if the -- the appropriate course of action is to be responsive to any queries, shall we say, that are still out there, and that's what we've been doing, as I said, providing definitive documents, where, before, there was summary documents, which we felt reflected the issue but was not necessarily the totally enriched document with schedules of numbers, et cetera, et cetera.

\* \* \*

*Steve Gold: One final question. Is the FDA currently awaiting any data or documents from Hemispherx that may be delaying this approval?*

[Carter]: *We don't think that there are any documents.* It's always hard to understand materiality, but there were many, for example, many inspections done all over the country.

The clinical site inspections, so far as I remember, were perfect. There were no so-called 483s, there were 483s – a small one issued on New Brunswick and a larger one issued on our – on our contract fill and finish group called Hollister Stier.

The 483 into the – into our facility, we believe, to the best of our satisfaction, roughly a month or six weeks ago. We haven't yet received a response from the agency on that, but that's not unusual for them simply to accept a response. And if they deem – if they still have a question, they may – they may inspect again. We haven't heard that they will.

We – I've commented in earlier inspections that with respect to Hollister Stier, there were some limited questions with respect to what's called mix and hold; that is, is the product being distributed in these very large tanks. We're still working on that. That's very common among perennial manufacturers to perfect that in, shall we say, the post-approval inspection. What we've done so far are pre-approval inspections, but there is still experiments that would necessarily have to be done in a post-approval and some of those we're – we're, shall we say, jumping the gun and – and doing them now in a – the hope that that will save time.

And, obviously, Hollister-Stier has an excellent reputation in this field, and we think that, ultimately that will carry the day. Though – though I would say that as of today we don't have evidence, written evidence, from the agency about Hollister Stier activity. We think that it will, as they've done many times in the past, be satisfactory to the regional office in Seattle which in turn will report that to the home office in Silver Spring, Maryland.

69. On August 10, 2009, the Company filed its quarterly report on Form 10-Q with the SEC for the quarter ended June 20, 2009, which stated in part:

On February 18, 2009, we were notified by the FDA that the originally scheduled Prescription Drug User Fee Act ("PDUFA") dated February 25, 2009 has been extended to May 25, 2009. On May 22, 2009, we were notified by the FDA that it may require up to one to two additional weeks to take action beyond the scheduled PDUFA action date of May 25, 2009. Since that date, no further notification has been received from the FDA.

\* \* \*

The FDA conducted a field inspection at Hollister-Stier Laboratories in Spokane, Washington in mid-2008. The Ampligen® final fill operations are performed under contract with Hollister-Stier. The inspection resulted in a FDA Form 483 with two observations dealing with reviews and validations of process variability. We continue to work with Hollister-Stier to finalize specific actions to address the FDA Form 483 issues and Hollister has submitted a specific action plan to the Seattle, Washington office of the FDA. It is our expectation that these issues will be resolved and we will be able to complete the resultant sequential validations by the end of 2009.

On September 19, 2008, we executed an agreement with Lovelace Respiratory Research Institute in Albuquerque, New Mexico to perform certain animal toxic studies in support of our Ampligen® NDA. These studies were requested by the FDA and will be done in collaboration with the resources of the New Brunswick facility. These studies have been substantially completed with summary reports expected to be issued to the FDA during the third quarter of 2009. Data for final

FDA reports are presently undergoing internal auditing at Lovelace and Hemispherx with a projected completion of the final report for late 2009 to early 2010.

70. On September 19, 2009, *TheStreet.com* published an article entitled “Hemispherx Hasn’t Called FDA on Ampligen Review,” which stated in part:

As the crowd [at the Rodman & Renshaw Global Investment Conference] was breaking up to make way for the next presenting company, I walked up to Carter, introduced myself, and asked him to more fully explain what he meant when he said the company was “cleaning up certain issues” with the FDA.

On numerous occasions since May, Carter has stated that the company wasn’t aware of any deficiencies in the Ampligen data package and that the FDA hasn’t asked the company for any additional information.

His answers to my question at the Rodman conference suggested a change to that stance. More specifically, I wanted Carter to explain why the company made a small but seemingly important alteration to the wording of its quarterly reports filed to the Securities and Exchange Commission.

Hemispherx is working with its contract manufacturer Hollister-Stier Laboratories to resolve two deficiencies in the Ampligen fill-finish process found by FDA inspectors working out of the agency’s district office in Seattle.

In previous quarterly reports to the SEC, Hemispherx stated that it, along with Hollister-Stier, had “submitted a specific action plan” to address the manufacturing deficiencies – known as 483 letter in FDA legal parlance – found by the FDA’s inspectors.

Hemispherx added new language to this section of its most recent 10-Q filed on Aug. 7. It reads: “It is our expectation that these issues will be resolved and we will be able to complete the resultant sequential validations by the end of 2009.”

This means that Hemispherx and its contract manufacturer are still working on the fixes to Ampligen’s manufacturing. And if the validation work won’t be done until the end of 2009, that means FDA won’t have a chance to review and/or approve the Ampligen manufacturing changes until well into 2010.

The new disclosure found in Hemispherx’s SEC filing doesn’t jibe with Carter’s previous statements in which he insisted that the FDA has not asked the company for any more information about Ampligen.

Clearly that’s not true. The FDA asked Hemispherx for information about Ampligen’s manufacturing and is now waiting for corrective actions to be taken.

*The FDA does not approve drugs with unresolved manufacturing issues.*

\* \* \*

I asked Carter about the new disclosures in his company's SEC filings and whether or not the unresolved manufacturing problems with Ampligen were delaying the drug's approval.

"I don't know. I'm not sure," he said, in response. Then he added, "Perhaps it's because the commissioner's husband worked for a hedge fund."

By commissioner, Carter was referring to newly appointed FDA Commissioner Margaret Hamburg, whose husband, Peter Fitzhugh Brown, is an officer at the hedge fund Renaissance Technologies. Brown had to divest certain stock holdings in drug companies held by the hedge fund before Hamburg could take her post. According to Carter, Brown's fund owned a stake in Hemispherx.

I explained to Carter that the FDA commissioner doesn't actually review drugs. This work is done by the various divisions of the FDA and that Ampligen's review, including the inspection of its manufacturing facilities, wouldn't have anything to do with whether or not Commissioner Hamburg's husband worked for a hedge fund or not.

"I have to go now, let's get out of here," said Carter as he walked away.

71. On October 9, 2009, during an interview with *biomedreports.com*, Defendant Carter made the following statements:

Interviewer: We have been contacted by so many members of the investment community who have asked us to contact you in regards to whether or not there has been communication between your Company and the FDA about the status of that drug application.

[Carter]: As I noted at some of the recent health care conference, we continue to be in contact with the agency concerning certain requests that they have made to us over the last year that have to do with what we call toxicology. This is non-clinical work on the drug which is customarily part of the new drug application. So we have continued to complete reports and we expect sometime this quarter, the fourth quarter, to complete a set of requirements that have to do with clinical toxicology – sorry, pre-clinical toxicology. Now, in addition to that, the agency has done a number of audits of our clinical sites as well as our manufacturing facility over the last 12 months. I'm very pleased to say that the clinical inspections resulted in no findings which required corrective action by the Company, which I believe is a very unusual positive result given the complexity and the duration of our clinical studies. However, the agency did note certain

compliance issues at our facility in New Brunswick, which we own, and also at a contract laboratory in Spokane, Washington, where we do something called fill and finish. We put the Ampligen into the final container. Now over the summer of 2009 we remediated the small compliance issues that existed in our own facilities and we submitted it to the regional office of the FDA which is in New Jersey. At the present time we are about to complete the remediation as we see it in the contract laboratory in Spokane. I believe that in the next several weeks that work will be completed and that will then generate a report to the regional office of the agency which is in Seattle, I believe. Now until all those reports are completed and filed satisfactorily with the agency, the agency can withhold a final decision on the commercialization of the product. But we believe that we will have achieved everything to the best of our knowledge which is necessary for a completion of what we call pre-approval inspections by the agency. So we would expect at any time thereafter to receive final comments from the FDA. I might add that our studies, which are very tedious and require using independent laboratories which we've had in New Mexico and in Pennsylvania, we have not uncovered any information which was deleterious to an approval of the product.

Interviewer: In one of the recent 10-Q's we find that in September 2008 you executed an agreement with Lovelace Respiratory Research Institute in New Mexico to perform certain animal toxic studies in support of that new drug application, and that these studies were requested by the FDA to be done in collaboration with the resources of your New Brunswick facility. These studies have been completed with summary reports that are presently undergoing auditing at Lovelace and are expected to be completed late 2009 or early 2010. It sounds like a check list that the FDA is going through in order to give you an approval or a decision on the approval. Is that accurate?

[Carter]: I think that's an accurate summary.

72. Defendants' statements about Hemispherx's application for FDA approval of Ampligen as a treatment for CFS alleged herein were materially false and misleading in that they misrepresented and concealed the fact that the Company need to submit multiple reports which were required by the FDA before the agency would act on the NDA, certain of which would take many additional months to produce, thus resulting in delay of FDA action by several months at a minimum.

**A. Defendants' November 2, 2009 Revelations**

73. On November 2, 2009, the Company issued a press release entitled "Hemispherx Biopharma Updates Chronic Fatigue Syndrome (CFS); Treatment and Commercial Application Programs; Targets Completion of All NDA Regulatory Responses and Initiation of Expanded Clinical Collaborations in CFS," which revealed that the FDA had told the Company well before May 2009 that numerous additional reports on numerous subjects were necessary before the agency could take action on the NDA, and that the Company did not expect to finish providing those reports until November or December 2009. The release stated in part:

The Company also plans to complete all outstanding queries from the FDA regarding its New Drug Application (NDA) for Ampligen®, an experimental therapeutic, during November and December, 2009. On May 26, 2009, the Company announced a delay on the Ampligen NDA which, at the time, had a PDUFA date of May 25, 2009. As noted in the 10-Q and 10-K filings at the time, the FDA did not request additional information from the Company at that time. However, several outstanding NDA items, requiring Hemispherx responses, existed at the time of the FDA delay as noted in the August 8, 2009, 10-Q filing. Between March 9, 2009 and September 15, 2009, the Company issued six (6) new reports to the Agency spanning various subjects including a) clinical safety assessments, b) specialized pre-clinical toxicology reports, and c) abbreviated chemistry and manufacturing control reports. The Company believes that these reports may fully retire all Agency queries in these particular areas.

The Company also plans to submit four (4) additional reports on interrelated topics in November and December, 2009, which will include pharmacokinetic analyses in multiple lower animal species (primates, rodents, etc.) ("the Lovelace Laboratory Studies") and final validation reports of certain manufacturing procedures conducted at an independent facility, Hollister-Stier Laboratories in Spokane, WA.

74. As a result of this disclosure, the price of Hemispherx's common stock dropped from \$1.45 per share on October 30, 2009, to close at \$1.33 per share on November 2, 2009 (an 8.28% decline) on unusually heavy volume of 2,409,294 shares traded; and declined further on November 3, 2009, when it closed at \$1.13 per share (a 15.04% decline), on unusually heavy volume of 8,739,506 shares traded. These decreases were a result of the disclosure of the facts

previously misrepresented and concealed by the Defendants, resulting in the partial dissipation of the artificial inflation of the price of the Company's stock caused by Defendants' misleading statements.

75. On November 3, 2009, *TheStreet.com* published an article entitled "Hemispherx Cops to Ampligen FDA Delay," which stated in part:

Hemispherx Biopharma issued an "update" to the regulatory status of its chronic fatigue syndrome drug Ampligen in which the Company essentially admits that its prior public statements were false and misleading.

Monday's statement was likely drafted by Hemispherx's lawyers as a way to help CEO Carter wiggle out of public statements he made in May and June claiming the Ampligen application to the U.S. Food and Drug Administration was to be complete. Carter insisted regulators weren't asking for any additional information on Ampligen.

Carter made these statements both before and immediately after the FDA approval decision date for Ampligen on May 25, which came and went without any word from the agency. *We now know that Carter's statements were demonstrably false. The FDA application for Ampligen was not complete because several items were outstanding, the Company now states.* These included FDA requests for data on Ampligen's safety both in humans and animals. The FDA also required additional information about Ampligen's manufacturing.

76. Following the November 2, 2009 announcement, a class action lawsuit was filed against Defendants, which Defendants told the investing public, in a November 16, 2009 press release, was "without merit." According to the November 16, 2009 press release, the allegation in that suit that the FDA had requested several reports before the agency could take action on the Company's Ampligen application was "irrefutably false," because the form letter received by the Company accepting the application for review (which is sent before the contents are reviewed) stated that the application was sufficiently complete to permit a substantial review, but did not explain why the complete review was delayed extensively. According to the November 16, 2009 press release, the Company was not required to disclose the requests for additional data. Further,

the press release did not disclose that questions had been raised as to whether there was any credible evidence of efficacy in the application, nor did it disclose the fact that the application would not be approved unless the FDA waived its requirement for usual and customary rodent carcinogenicity studies where a drug is to be taken regularly for a chronic condition for years.

**B. Defendants' December 1, 2009 Revelations**

77. On December 1, 2009, after the market closed, the Company issued a press release disclosing the FDA's conclusion that the Company's application for Ampligen was not approvable because, among other things, it did not provide credible evidence of efficacy and other deficiencies cited by the reviewers. The FDA reached that conclusion because the Company's Phase III clinical trial did not produce statistically significant results for the intent to treat analysis, which the FDA requires. The December 1, 2009 press release also disclosed that the Company had failed to satisfy FDA requirements to perform well-controlled testing for QT interval cardiac irregularities and that the new clinical trial would need to include such testing, which revealed that Defendant Strayer's Class Period representations about QT interval testing, as alleged herein, were materially false and misleading. The press release further disclosed the fact that Defendants concealed that the NDA had not included the required animal carcinogenicity studies because the Company asked for a waiver of that requirement, which was denied. The December 1, 2009 press release stated:

*Most notably, the FDA stated that the two primary clinical studies submitted with the NDA did not provide credible evidence of efficacy of Ampligen(R) and recommends at least one additional clinical study which shows a convincing effect and confirms safety in the target population. The FDA indicated that the additional study should be of sufficient size and sufficient duration (6 months) and include appropriate monitoring to rule out the generation of autoimmune disease. In addition, patients in the study should be on more than one dose regimen, including at least 300 patients on dose regimens intended for marketing. Finally, the additional study must incorporate both a well-controlled QT interval study and pharmacokinetic evaluations.*

Other items required by the FDA include certain aspects of Non-Clinical safety assessment, and Product Quality. In the Non-Clinical area, *the FDA is recommending that the Company complete rodent carcinogenicity studies in two species. As part of the NDA submission, the Company had requested that these studies be waived, but the waiver has not been granted.* Certain additional non-clinical studies and additional data to support non-clinical studies already submitted with the NDA are also recommended by the FDA. *Prior to the receipt of the Complete Response letter, the Company had already begun many of these additional studies and the collection of the requested additional data.*

Under the Product Quality section of the Complete Response letter, the FDA recommends that the Company submit additional data and complete various analytical procedures. The collection of these data and the completion of these procedures is already part of the Company's ongoing Quality Control, Quality Assurance program for Ampligen(R) manufacturing under cGMP (current Good Manufacturing Practice Guidelines) and the manufacturing enhancement program recently undertaken by the Company and announced in a news release on September 16, 2009.

Finally, the FDA commented on Ampligen(R) manufacturing noting the need to resolve outstanding inspection issues at the facilities producing Ampligen(R). These include the Company facility located in New Brunswick, NJ and one of the Company's third party manufacturing facilities (Hollister-Stier Laboratories). The Company has been working to resolve these issues.

At this time the Company's management has not determined the impact of the additional recommendations set forth in the Complete Response letter on the timelines and overall cost of the Ampligen(R) program, but the Company's management has made response to the issues and satisfaction of any additional requirements a top priority. The Company will seek to meet with the FDA to clarify any issues identified in the Complete Response letter and to work with the FDA to identify the most expeditious path to satisfaction of the requirements for approval of the Ampligen(R) NDA.

78. As a result of the foregoing disclosures in the December 1, 2009 press release, the price of Hemispherx stock fell an additional \$0.49 per share, from a closing price of \$1.20 per share on December 1, 2009, to close at \$0.71 per share on December 2, 2009 (a 40.83% decline), on extraordinary volume of 26,168,813 shares traded; and declined further on December 3, 2009, when it closed at \$0.68 per share (a 4.23% decline), on unusually heavy volume of 7,510,378 shares traded.

79. The revelation of Defendants' misrepresentations including that the results of the Phase III clinical trial for intent to treat analysis were statistically significant and misrepresentations about QT interval testing, as alleged herein, were a substantial cause of the decline in the stock price.

80. A December 2, 2009 article in *TheStreet.com* described the FDA action and its dire consequences for Hemispherx as follows:

Hemispherx BioPharma ... said late Tuesday night that the Food and Drug Administration refused to approve the experimental drug Ampligen for use in patients with chronic fatigue syndrome.

The regulatory agency's rejection of Ampligen is a staggering blow to Hemispherx, which has pursued the drug's development in a dizzying array of diseases for more than 20 years with no success.

Hemispherx shares plunged 43% to 68 cents in early Wednesday trading.

*The FDA's complete response letter to Hemispherx – summarized in the company's Tuesday night press release – essentially instructs Hemispherx to start Ampligen's clinical trial program from scratch.*

*The agency's medical reviewers concluded that the two clinical studies of Ampligen submitted by Hemispherx "did not provide credible evidence of efficacy," according to the company.*

In order to reconsider Ampligen for review, the FDA instructed Hemispherx to conduct at least one additional clinical study in chronic fatigue syndrome. The study needs to test different doses of Ampligen for a minimum of six months, including at least 300 patients on Ampligen dose regimens intended for marketing, according to Hemispherx's summation of the FDA's letter.

Hemispherx could find meeting the FDA's demand exceedingly difficult and expensive. If the FDA requires 300 patients treated with Ampligen in a new pivotal study, for example, Hemispherx would probably have to enroll 450 total patients at a minimum (assuming two patients treated with Ampligen for every one patient treated with a placebo to act as a control.)

*But the FDA is asking for even more from Hemispherx, including tests of Ampligen in rodents to rule out the risk of cancer and a safety study in humans to ensure that Ampligen doesn't cause dangerous changes to a patient's heart rhythm.*

Ampligen's manufacturing problems, previously flagged by FDA inspectors, also remain unresolved, the company said Tuesday.

**VII. FACTS WHICH GIVE RISE TO A COGENT INFERENCE OF SCIENTER**

81. The following facts provide support for the strong inference of Defendants' scienter:

82. During the Class Period, Defendants had both the motive and opportunity to conduct fraud. They had motive to decide to permit the Company to sell more than \$61.8 million of its securities to raise badly needed funds. They also knew what the Company had submitted to the FDA and had knowledge of the misleading nature of the statements they made or acted in reckless disregard of the true information known to them at the time. In so doing, Defendants participated in a scheme to defraud and committed acts and practices and participated in a course of business that operated as a fraud or deceit on purchasers of Hemispherx common stock during the Class Period.

**A. Defendants Were Motivated to Commit Fraud in Order to Sell More Than \$61.8 Million of Artificially Inflated Securities During the Class Period**

**1. Defendant Carter Entered into a Standby Financing Agreement that Obligated Him to Personally Finance the Company's Operations if Hemispherx Was Unable to Obtain Other Financing**

83. Defendant Carter was highly motivated to commit fraud so that the Company could raise money through Class Period securities offerings because, in February 2009, he entered into a Standby Financing Agreement with Hemispherx in which he agreed personally to loan the Company up to \$1,000,000 to maintain the Company's operations if the Company was unable to obtain other financing in 2009 through securities offerings or other outside financing agreements. Thus, Defendant Carter's obligations under the Standby Financing Agreement gave him a strong motive to make false statements concerning positive short-term prospects for FDA

approval of the Ampligen NDA so that Hemispherx could successfully raise money from securities offerings, which allowed him to avoid having to finance personally the Company's operations.

**2. Defendants Were Motivated to Artificially Inflate the Price of Hemispherx Stock to Profit from Class Period Securities Offerings**

84. Defendants were highly motivated to commit the fraud alleged herein in order to artificially boost the prices of Hemispherx common stock during the Class Period in order to profit from the following Class Period securities offerings, in which the offering prices of Hemispherx securities were based on the prevailing artificially inflated market prices of the Company's shares at the time of sales:

- a. On May 8, 2009, the Company entered into an agreement with Rodman & Renshaw, LLC as placement agent, relating to a proposed offering of the Company's securities. Thereafter, on May 10, 2009, the Company entered into Securities Purchase Agreements with two institutional investors. Pursuant to the Securities Purchase Agreements, the Company issued to these investors in the aggregate: (a) 13,636,363 shares of Company common stock at \$1.10 per share in exchange for \$15 million cash; (b) Series I warrants to purchase an additional 6,136,363 shares of Company common stock at an exercise price of \$1.65 per share; and (c) Series II warrants to purchase up to 3,000,000 shares of Company common stock at an exercise price of \$1.10 per share. The Series I warrants can be exercised at any time on or after the six month anniversary of the May 18, 2009 closing date of the offering and for a five year period thereafter. The Series II warrants could be exercised at any time on or after the May 18, 2009 date of delivery of the Series II warrants and for a period of 45 days thereafter. As of

September 30, 2009, all Series II warrants were exercised and none of the Series I warrants were yet eligible for exercise.

- b. On May 18, 2009, the Company entered into Securities Purchase Agreements with two institutional investors. Pursuant to the Securities Purchase Agreements, the Company issued to these investors in the aggregate: (a) 11,906,976 shares of Company common stock at \$1.34375 per share in exchange for \$16 million cash; and (b) warrants to purchase an additional 4,167,440 shares of common stock at an exercise price \$1.31 per share. The warrants can be exercised at any time on or after their May 21, 2009 date of issuance and for a five year period thereafter. As of September 30, 2009, 1,895,000 of these warrants had been exercised.
- c. *As a result of the May 8, 2009 and May 18, 2009 Securities Purchase Agreements, Defendants raised in the aggregate approximately \$33,712,000 for the Company, net of all related offering costs, including the fair value of warrants issued.*
- d. On July 2, 2008, the Company entered into a \$30 million Common Stock Purchase Agreement (the "Purchase Agreement") with Fusion Capital Fund II, LLC ("Fusion Capital"), an Illinois limited liability company. Concurrently with entering into the Purchase Agreement, the Company entered into a registration rights agreement with Fusion Capital. Under the registration rights agreement, Hemispherx filed a registration statement related to the transaction with the SEC covering the shares that had been issued or may be issued to Fusion Capital under the common stock purchase agreement. That registration statement was declared effective by the SEC on August 12, 2008. As reported in the registration

statement related to the transaction, Hemispherx had the right over a 25 month period beginning August 2008 to sell its shares of common stock to Fusion Capital from time to time, in amounts between \$120,000 and \$1 million, depending on certain conditions as set forth in the agreement, up to a maximum of \$30 million. *The purchase price of the shares related to the \$30.0 million of future funding was based on the prevailing market prices of the Company's shares at the time of sales as computed under the Purchase Agreement without any fixed discount, and the Company had control of the timing and amount of any sales of shares to Fusion Capital. However, Fusion Capital could not purchase any shares of Hemispherx common stock pursuant to the Purchase Agreement if the price of Hemispherx common stock had three trading days with an average value below \$0.40 over the prior twelve trading days.* As of September 1, 2009, Fusion Capital had purchased the maximum number of shares that were registered under the Registration Statement, an aggregate of 20,000,000 shares and received 1,259,086 commitment shares. *As a result of the July 2, 2008 Common Stock Purchase Agreement, Defendants raised \$28,111,695 for the Company.*

85. Defendants also were motivated to complete these securities offerings and raise more than \$61.8 million so that they could embark on a grandiose plan to manufacture massive quantities of Alpheron LDO and Ampligen for investigation and possible clinical trials as flu vaccine adjuvants, a project that Defendant Carter stated in the July 22, 2009 conference call, would involve investing more than \$10 million of the Company's newly raised capital:

[Carter]: Now, we are – we are targeting in the in our presentation today, we're targeting a capacity to produce 25 to 50 million doses per year of the vaccine

adjuvant Ampligen. And this is based on the work of Dr. Hasegawa, which I'll highlight again in a moment.

We're also targeting the capacity to make at least 100 million doses of the Alpheron LDO product on an annualized basis.

In order to do this, we're making significant investments in infrastructure and in clinical trials and immediately will be expending more than \$10 million to lay – lay in place an infrastructure to meet these – these goals.

**B. Defendant Carter Tightly Controlled All Hemispherx Communications with the FDA**

86. Defendant Carter's scienter is supported by a statement from a former Hemispherx employee, who confirms that all of the Company's communications with the FDA went through Defendant Carter. Specifically, a former Hemispherx employee who worked at the Company's headquarters from 1999 through the end of 2008 and worked closely with Defendant Carter in an administrative capacity states: "*That Dr. Carter tightly controlled the communication channel between Hemispherx and the FDA was an understatement. Everything went through him or not at all.*" This former employee also said, "*Dr. Carter did not want any of the information that was going back and forth to the FDA regarding Ampligen to get out into public knowledge until he wanted it to get out.*" As a result, Defendant Carter had actual knowledge of the FDA's requests for additional reports during the Class Period and the reasons for the delays of the PDUFA date, among other things.

**C. The Company Admits in its SEC Filings That Defendant Carter Was Knowledgeable About the Company's Clinical Trials**

87. Under risk factors, Hemispherx's Class Period SEC filings single out as the Company's key man Defendant Carter, the co-inventor of Ampligen, because of "his knowledge of [the Company's] overall activities, including ... clinical trials," stating:

*The loss of services of key personnel including Dr. William A. Carter could hurt our chances for success.*

Our success is dependent on the continued efforts of our staff, especially certain doctors and researchers along with the continued efforts of Dr. William A. Carter because of his position as a pioneer in the field of nucleic acid drugs, *his being the co-inventor of Ampligen®, and his knowledge of our overall activities, including patents and clinical trials.* The loss of the services of personnel key to our operations or *Dr. Carter could have a material adverse effect on our operations and chances for success.* As a cash conservation measure, we have elected to discontinue the Key Man life insurance in the amount of \$2,000,000 on the life of Dr. Carter until we receive regulatory clearance for Ampligen®. An employment agreement continues to exist with Dr. Carter that, as amended, runs until December 31, 2010. However, Dr. Carter has the right to terminate his employment upon not less than 30 days prior written notice. The loss of Dr. Carter or other personnel or the failure to recruit additional personnel as needed could have a materially adverse effect on our ability to achieve our objectives.

Hemispherx Form 10-Q filed with the SEC on November 9, 2009.

**D. Defendants Knew That Carcinogenicity Studies and a Third Clinical Trial Were Needed to Prove Safety and Efficacy, But Represented Publicly That They Were Not Needed to Obtain FDA Approval**

88. During an investor conference call on December 3, 2009, Defendant Carter admitted that the FDA's request for an additional third clinical trial was not unexpected because the FDA had required a similar study in the case of Pfizer's Lyrica, a drug for Fibromyalgia (a disease with significant overlap with CFS). Specifically, Defendant Carter stated:

*Now a bit about the history of Chronic Fatigue Syndrome and a related disease, which is called fibromyalgia syndrome, FMS. These are two sister diseases, which have about a 20% overlap. By that I mean, you can meet the diagnostic criteria for either disease with the same symptoms in about 20% of the patients.*

You may remember that the pioneering company in fibromyalgia has been Pfizer in a product called Lyrica. A couple of years ago, notwithstanding the fact that they had two well-controlled studies, *Pfizer was requested by the agency as a preapproval requirement to conduct a third study.* You can confirm this by looking in the package insert.

In the instance of Lyrica in fibromyalgia they were able to use the treatment IND patients and basically wean them off-drug and look at the response pattern. *So there are significant historical analogies here between the fibromyalgia successes and what we believe may be the successes with Chronic Fatigue Syndrome.*

*A third trial is not unexpected in a situation where you're dealing with a large disease category, in this case these diseases may have as many as 4 million subjects. And of course there are no – there were no drugs on the market for fibromyalgia until Lyrica, and in the case of Chronic Fatigue Syndrome, obviously there are no other drugs on the market, and indeed Ampligen is the only product, which has the emergency treatment IND provision.*

89. In fact, Defendant Carter had recognized the similarities between the Lyrica NDA and Hemispherx's Ampligen NDA at least as early as April 2008, and thus, knew of or recklessly disregarded that a third clinical trial, like the one required for Lyrica, would be needed for Ampligen, but Defendants filed the Ampligen NDA without performing this trial. In fact, Defendant Carter represented that additional studies would not be needed to obtain FDA approval.

90. Specifically, in an April 9, 2008 conference call, Defendant Carter stated: “[W]e do not believe any additional studies will be needed to complete the NDA filing status presumptively to go forward with a total application and receive a favorable review.” Also during this conference call, Defendant Carter highlighted the similarities between the Ampligen NDA and Pfizer's successful application for Lyrica, a drug for Fibromyalgia, stating:

I think part of the wind in our sail in this area is the fact that the fibromyalgia launch of Pfizer in July 2007 – that is the sister disease of chronic fatigue – seems to be going tremendously well and is based on the marketing advertising for Lyrica. And you will remember that in the early days of fibromyalgia much like Chronic Fatigue Syndrome, there was a lot of skepticism about the seriousness of the (inaudible), the success of Lyrica is definitely retiring (inaudible) areas of concern.

91. In the December 3, 2009 conference call, Defendant Carter said that he believed that the third clinical trial would proceed quickly and admitted that, at the time Hemispherx received the FDA's Complete Review Letter in December 2009, the Company had already engaged clinical review organizations (“CRO”) to facilitate enrollment of patients for the third clinical trial prior to receiving the FDA's complete review letter.

92. Defendants' decision to engage CROs prior to receiving the Complete Review Letter provides further support for a strong inference of Defendant Carter's scienter or actual knowledge that the FDA would reject the Ampligen NDA and require a third clinical trial, as there would be no reason to do so unless he reasonably expected that the NDA would be rejected for failing to prove efficacy and that a new clinical trial would be needed to do so.

93. Defendants knew that Hemispherx needed to perform carcinogenicity studies because the Company had requested a waiver from such studies, which was denied. Nonetheless, in May and June 2009, Defendant Carter made statements that the Ampligen NDA was complete. He made these statements before and after the May 2009 PDUFA date, which came and went without FDA action. As reported on November 3, 2009 by *TheStreet.com*: "**We now know that Carter's statements were demonstrably false. The FDA application for Ampligen was not complete because several items were outstanding, the Company now states. These included FDA requests for data on Ampligen's safety both in humans and animals. The FDA also required additional information about Ampligen's manufacturing.**"

94. Defendant Carter's public statements helped to boost the price of Hemispherx's common stock and also helped when the Company offered for sale more than \$61.8 million of its securities during the Class Period. Hemispherx's stock traded for around 50 cents for most of the first half of 2009, but zoomed to a high of \$1.93 on May 18, 2009 on Company-induced mania that FDA approval was soon approaching.

95. The Company had requested a waiver of carcinogenicity studies and did not do a third clinical trial (which they later admitted was needed to secure FDA approval) despite Defendants' knowledge that the FDA had required such trials in the case of similar applications.

Before filing the Ampligen NDA in October 2007 (as amended in April 2008), Defendants did not do a third clinical trial because Hemispherx was rapidly burning through its dwindling cash reserves and could not conceivably afford to do these studies.

96. Instead, Defendants first filed the Ampligen NDA so that they could hype its prospects for the near-term approval of Ampligen when they went to raise money by offering for sale more than \$61.8 million of the Company's securities during the Class Period. Indeed, having raised this money through the Class Period securities offerings, Defendant Carter declared at the December 3, 2009 conference call that "the Company has ... the financial strength to execute these studies on a timely basis." Hemispherx would not have had the financial ability to conduct new clinical trials but for the Class Period securities offerings, as the Company reported cash and cash equivalents of only \$6.1 million as of December 31, 2008 (before the offerings), but at the end of the third quarter of 2009 (September 31, 2009), the Company reported cash and cash equivalents of more than \$61 million. This cash was not generated from the Company's operations, as the Company reported total revenue of only \$25,000 for the third quarter of 2009, which was a typical quarter for Hemispherx.

**E. Defendants' Extensive and Frequent Investor Conference Call Discussions Concerning the Ampligen NDA Further Support a Strong Inference of Their Scienter**

97. Defendant Carter's extensive and detailed discussions concerning the Ampligen NDA during Hemispherx's investor conference calls, both before and during the Class Period, provide further support for a strong inference of his scienter. Indeed, Defendant Carter's and Strayer's discussions concerning the Ampligen NDA dominated the conference calls and demonstrate that Ampligen was Hemispherx's core product and that FDA approval of this drug for treatment of CFS was vital to the Company's future financial results and its viability.

98. For example, during the December 19, 2007 conference call, Defendant Carter emphasized Hemispherx's interest in obtaining FDA approval for Ampligen by noting that the royalty interest alone for the Pfizer drug Lyrica (which is used to treat fibromyalgia, a sister disorder to CFS) had recently been sold for \$700 million. Defendant Carter stated that:

So we continue to believe that not only is this a large, and obviously underserved market – especially the chronic fatigue syndrome piece – but that it also holds great economic benefit to the entity or entities which ultimately are able to launch products into this space. And of course as you know at this time, Hemispherx is the only company that has a treatment IND; it's the only company that has done Phase III studies, et cetera ... it looks like a bountiful harvest for the company who ultimately succeeds...

99. During the April 9, 2008 conference call, Defendant Carter noted that, in anticipation of an FDA response concerning the Ampligen NDA, the Company was "looking for more further peer reviewed articles as well and potentially link strategic partnerships in the chronic fatigue space," and stated that "[r]ecognizing that these are big enchiladas, this is a major area where the Company has to choose its partnerships very carefully..."

100. In addition, during the July 17, 2008 conference call, Defendant Carter stated that it was "estimated that the total number of patients who have [ ] [fibromyalgia and/or CFS] is about 10 million patients – 10 million people" and that "[t]he important thing to remember from the point of view of a Hemispherx investor is that the key differentiating product in this whole space right now is Ampligen ... [b]ecause it is the only product that has advanced clinical data showing that the constellation of symptoms which primarily includes fatigue, but also include cognitive dysfunction, sleep disorders, headaches, etc., etc., sore throat ... appear to be treated by [Algra] based on the peer review to articles and the well-controlled studies." Defendant Carter also noted during this conference call that fibromyalgia drugs Lyrica and Cymbalta (made by Lilly) were projected to generate annual revenues of \$2.4 billion and \$2 billion respectively.

101. In addition, during the July 17, 2008 conference call, one of the Company's founders asked how long it takes "[f]or an old-timer to come of age," to which Defendant Carter responded:

You are one of the original founders of this Company. One of the original shareholders and I would just say it has been a long road and it's been 20, 20-something year road. During this time a lot of money has been spent not only by us, but by the competition.

I think that where it is all going to come down here, Fred, is that the structure of this drug – and I'm talking now solely about the Ampligen part – the structure of this drug is unique and we knew many years ago did the initial licensing from Johns Hopkins University, when you and [Joe Hanson] came over there from Rockville, I think that was a very critical point in history.

Because although there have been many efforts especially recently to try to mimic the unique structure of that drug, none this far have been successful. I think that's what gets – what is going to get us over the final hurdle here, is the safety combined with advocacy and that is what you and Joe Hanson realized I think years ago when you came over to Hopkins to talk to the licensing department ... I think we are looking at some good times ahead.

102. Defendant Carter further acknowledged the significance of Ampligen to Hemispherx during the March 19, 2009, conference call by noting that the Company was preparing to reinstate commercial sales of its product Alferon N, "which were basically put on hold not only for economic reasons but because of staff had to be redeployed for this major undertaking in the Ampligen New Drug Application." In addition, Defendant Carter explained that it was crucial for data showing the effectiveness of Ampligen to be accepted by the FDA, physicians, and reimbursement specialists because "a drug in [its] class would certainly have the potential to be a \$1 billion product assuming it was accepted in the marketplace ..."

103. Similarly, a strong inference of Defendant Strayer's scienter is supported by his role as Hemispherx's Medical Director, in which he was responsible for and had control over the particular activities that were falsely reported to investors during the Class Period – the clinical

trials of Ampligen and the NDA. Moreover, as alleged herein, at medical conferences Defendant Strayer served as the Company's spokesperson about the Ampligen clinical trials and NDA and during investor conference calls he regularly reported to the public about the clinical trials and the status of the Ampligen NDA.

**F. Defendants Were Motivated to Commit Fraud in Order to Reward Themselves with Lucrative Bonus Compensation**

104. Defendants Carter and Strayer were also strongly motivated to misrepresent Hemispherx's prospects for approval of the Ampligen NDA because of the potential to receive enormous incentive-based cash bonuses and stock-based awards. Specifically, as detailed in a report on Form 8-K filed with the SEC on May 27, 2009 and a Company press release issued the same day, Defendant Carter caused himself to be awarded \$300,000 and Defendant Strayer to be awarded \$150,000 for getting the NDA filed (notwithstanding the deficiencies in the design of its Phase III clinical trial and the Company's futile attempts to obtain a waiver of necessary safety testing, including a carcinogenicity study and a well-controlled QT interval study), and for raising desperately needed cash by lying to investors about the prospects for approval of Ampligen, stating:

[O]n May 20, 2009, our Board of Directors awarded bonuses to the following executives in relation to 2008 corporate goals and objectives: W.A. Carter, M.D., CEO and Chairman of the Board, was awarded \$300,000 and Dr. David Strayer, Chief Medical Officer, was awarded \$150,000.

The Compensation Committee and Board of Directors reviewed corporate goals established in March 2008 and determined that significant progress has been made in terms of 1) **preparation and filing the Ampligen® NDA with the Federal Drug Administration**; and 2) with the receipt of recent funding for operating activities, funds previously reserved for operating activities could be used to pay 2008 bonus.

105. Despite the spectacular failure of the Ampligen NDA and the embarrassment of being called out by the financial press for lying to the investing public about the reasons for the

delays of the PDUFA date, on or about February 10, 2010 Defendant Carter, acting in his role as Chairman of the Board of Directors, saw fit to siphon off a portion of the cash raised in the Company's Class Period securities offerings in order to pay himself and his acolytes lucrative year-end bonuses. Specifically, the Company's February 10, 2010 press release revealed that Defendant Carter caused himself to be granted the largest bonus of \$182,772 and Defendant Strayer received the second largest of \$44,306. The February 10, 2010 press release stated:

The Compensation Committee and Board of Directors reviewed the individual achievements of each bonus eligible individual, along with their contribution towards meeting corporate goals established in May 2009, and determined that bonuses were justifiable based on significant progress made in terms of:

1. Attainment of favorable FDA response to utilize a subcontractor for the manufacture of Ampligen®;
2. Continued development and study of Ampligen® as an adjuvant potentially enhancing the effectiveness of vaccines against microbial infection;
3. Success in the protection of Company intellectual property;
4. Continued development of Alferon® LDO; and
5. Maintaining the overall financial strength of the Company and operations consistent with the Board approved budget.

As a result of their review, the Compensation Committee has recommended and Board of Directors approved the award of bonus to Dr. William Carter, Chairman & CEO (\$182,772), Charles Bernhardt, CFO & Chief Accounting Officer (\$44,000), Dr. David Strayer, Medical Director (\$44,306) and Wayne Springate, V.P. of Operations (\$33,000) and certain others.

**G. A Strong Inference of Defendants' Scienter Is Further Supported by the FDA's Post-Submission Guidelines for Communications with Applicants, Through Which Defendants Learned of or Recklessly Disregarded the Reasons for the Delays of the PDUFA Date and Deficiencies in the NDA**

106. While Defendants' Class Period statements depict the FDA as being silent concerning its ongoing review of the NDA during the Class Period and, in particular, not seeking

additional information concerning Ampligen (assertions Defendants eventually admitted were false in the November 2, 2009 press release), FDA publications concerning post-submission procedures paint an extremely different picture of the agency than Defendants. Specifically, FDA guidelines on “good review management principles and practices” (“GRMPs”) promote engaging “applicants in productive communications during product development (the investigational new drug application (IND) phase) and marketing application review.” FDA, Center for Drug Evaluation and Research, *Guidance for Review Staff and Industry Good Review Management Principles and Practices for PDUFA Products*, at 2 (April 2005). Indeed, the “GRMPs outline the FDA’s procedures and objectives for communicating with applicants [like Hemispherx] during each phase of the review cycle,” including the post-NDA submission phase. *Id.* One of the goals of these procedures is to prevent applicants from being surprised by the results of the agency’s review of an NDA and to provide “clarity of the FDA’s findings, expectations and bases for decisions...,” through “[c]ommunications during the ongoing review, within CDER and CBER or with external groups such as the applicant or advisory committees....” *Id.* at 3. Another goal of the GRMPs is “transparency,” which “ensures that review staff and applicants are kept informed of how the review is progressing.” *Id.* at 4. The GRMPs also state: “Applicants may receive additional information requests as a result of ongoing reviews and are encouraged to respond promptly and completely to such requests.” *Id.* at 16.

107. The FDA’s GRMPs also require “[e]ffective and timely communication between the FDA and applicants,” particularly with respect to deficiencies in the NDA that may affect approval. Specifically, the GRMPs state:

For applicants found to have significant deficiencies that may affect approval, the review team should obtain appropriate input for the signatory authority and

communicate the deficiencies promptly to the applicant. **Timely notification of correctable deficiencies allows the applicant to begin corrective actions, maximizes the chances for a first cycle approval, and shortens the overall time to approval when one or more review cycles are necessary.** Timely notification of significant and potentially uncorrectable deficiencies in the marketing application may also influence product development decisions.

*Id.* at 7.

108. Moreover, the FDA's "user fee goals include mechanisms to improve communications about potential deficiencies during the review cycle. For example, the Goals Letter (2002) states that it is the intention of CDER and CBER to notify a sponsor of deficiencies in an application when each discipline has finished its initial review of its section of the pending application. In addition, the Goals Letter states that the review division and the safety group assigned to the review of a particular application will try to communicate their comments on a proposed risk management tool and plan, as well as on protocols for observational studies, as early in the review process as possible." 73 Fed. Reg. 39594 (July 10, 2008).

109. FDA regulations also take into account the extent of deficiencies in an NDA. FDA regulations classify deficiencies as "minor" if they can be corrected by, for example, making labeling changes. FDA regulations classify deficiencies as "major" if (as in the instant case) they can only be corrected by conducting new clinical trials.

110. Thus, based on GRMPs and other FDA regulations, Defendants would have been alerted to the major deficiencies in the Ampligen NDA long before they received the FDA's complete review letter. In fact, the Defendants' admission in the November 2, 2009 press release that Hemispherx had submitted numerous reports to the FDA during the Class Period and was continuing to provide further reports on several topics further supports the strong inference that, in this case, the staff of the FDA was following GRMPs and had communicated to Defendants

that the staff had found deficiencies that would be fatal to first cycle approval of the Ampligen NDA.

111. While Defendants falsely attributed delays in the PDUFA date to FDA staffing problems and other administrative issues, the GRMPs indicate that the FDA “[s]taff should communicate any significant changes in the review timeline to the applicant.” *Guidance for Review Staff and Industry GRMPs*, at 6. Moreover, the GRMPs specify that changes in the review timeline “can stem from … requests for additional data or analyses from the applicant,” as was the case with the Ampligen NDA. *Id.* Thus, under GRMPs, Defendants would have been well-informed by FDA staff as to the reasons for the delays in the PDUFA date and could not have reasonably believed that the delays were due to FDA staffing issues or some other bureaucratic logjam, as they reported to the investing public.

**H. Defendant Carter’s False Explanations of the Delay Further Support a Strong Inference of His Scienter**

112. When asked at an investors’ conference in September 2009 about the reason for the delay in FDA action, Defendant Carter said “I don’t know. I’m not sure. Perhaps it’s because the Commissioner’s husband worked for a hedge fund [which owned Hemispherx shares].” As the Complete Review letter showed and as Defendant Carter admitted at the end of the Class Period, the reasons for the FDA’s delay related to the multiple deficiencies in Hemispherx’s NDA. Moreover, when Defendant Carter made this extraordinary assertion (as it strains credulity to suggest that an FDA Commissioner would play any role in making decisions about action on an individual NDA), he knew that he had asked for a waiver of carcinogenicity studies (which are normally required) and he expected that the FDA would require a third clinical trial as it had in the case of similar applications involving Pfizer’s drug Lyrica (Pregabalin) for treatment of Fibromyalgia (a condition that has significant overlap with CFS).

**I. A Strong Inference of Scienter Is Further Supported by Defendants' History of FDA Reprimands for Making False Statements About Ampligen**

113. On at least two occasions, the FDA has reprimanded Defendants, and in particular Defendant Carter, for improperly making statements promoting Ampligen as a safe and effective drug for treatment of CFS prior to receiving marketing approval from the FDA. Specifically, in an October 15, 1998 letter addressed to Defendant Carter, the FDA stated that Hemispherx had violated the Food, Drug, and Cosmetic Act and applicable regulations by making claims of safety and efficacy for the purpose for which it was under investigation, stating:

This letter concerns materials released by Hemispherx Biopharma, Inc. (Hemispherx) regarding its drug Ampligen, which currently has investigational new drug status with the Food and Drug Administration. As part of its monitoring program, the Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed the Hemispherx Products Page on the Hemispherx website, a press release issued by Hemispherx on September 21, 1998, and a Hemispherx Biopharma teleconference recorded on September 23, 1998.

**After reviewing these materials, DDMAC has determined that Hemispherx is promoting Ampligen as a safe and effective drug prior to its approval for marketing. Promoting drugs prior to their approval violates the Food, Drug, and Cosmetic Act, and regulations promulgated thereunder.**

The regulations at 21 C.F.R. 312.7, specifically state that a "sponsor, investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purpose for which it is under investigation or otherwise promote the drug." The intent of the regulation is not to inhibit the exchange of scientific findings, but to prevent dissemination of promotional claims of safety or efficacy of an investigational drug, and to "preclude commercialization of the drug before it is approved for commercial distribution."

Hemispherx has made the following promotional claims about Ampligen as DDMAC has outlined below (not all inclusive):

**Hemispherx Products Page on Website**

- **Chronic Fatigue and Immune Dysfunction Syndrome (CFIDS)**  
"Ampligen . . . has shown efficacy and safety in a completed Phase II study; recent clinical trials in Belgium have shown an 80% complete recovery in CFS patients."

\* \* \*

**Press Release issued by Hemispherx on September 21, 1998: Hemispherx Biopharma, Inc.: CFS Advocacy Group Says Ampligen Works and is Needed Immediately!!**

- "... Ampligen is an especially safe drug."
- "The disease has gone down a rocky path, and then after some 15 years of futile research as to the cause of the illness or a cure, a drug emerges that has shown tremendous promise. Life is now meaningful, because a debilitated person who cannot climb a flight of stairs is now able to climb unassisted. A person who cannot rise from a toilet before therapy is able to stand, walk, and perform household chores. Life that was spent in bed, resting and looking at the ceiling, is now spent cherishing moments of opportunity in a lifetime ahead of fulfilling personal goals, all due to the intervention of Ampligen therapy."
- "In short, the defective immune systems of many CFS patients have been repaired by Ampligen."
- "... people who have made major sacrifices in finding the money to be on this life-saving, life-reclaiming drug."

**Hemispherx Biopharma Teleconference (recorded September 23, 1998)**

- Ampligen provides "statistical improvement in physical performance, mental skills, etc., and in the constellation of activities we call medically, the quality of life."
- \* \* \*
- Ampligen is the only effective, promising treatment for Chronic Fatigue Syndrome.

\* \* \*

**Hemispherx should immediately discontinue the dissemination of materials that make claims of safety or efficacy for Ampligen....**

114. Despite this strong reprimand by the FDA, Defendants continued to publicly make claims about the purported safety and efficacy of Ampligen and, as a result, on July 7, 2000, the FDA issued another letter addressed to Defendant Carter in which the FDA again reprimanded Defendants for continuing to make similar claims in violation of federal law, stating:

We previously issued an untitled letter, dated October 15, 1998, to Hemispherx for promoting Ampligen as safe or effective while the product was under investigation. In our letter, we informed you that your activities were in violation

of the Act and applicable regulations. In your response, dated October 29, 1998, you assured us that Hemispherx would discontinue or revise all materials concerning Ampligen to conform with the Act and regulations.

However, notwithstanding your assurances, you continue to promote Ampligen as safe and effective prior to approval in your press releases and on your Internet website. Such activities constitute promotion of an investigational new drug as safe or effective in violation of the Act and its implementing regulations. In addition, your promotional materials are false and misleading in that they fail to disclose facts that are material in light of representations made about Ampligen.

\* \* \*

#### INTERNET WEBSITE

Although some of the materials referenced below were originally issued by third parties, this letter does not concern the third parties or their original communications.

Your website, [www.hemispherx.com](http://www.hemispherx.com), contained a direct link to transcripts of Dr. Mazlen's CFS Radio Program, which promote Ampligen as safe and effective. For example, the linked transcript from Dr. Maxlen's CFS Radio Program from February 28, 1999, presents the following conversation between Dr. Mazlen and Dr. Paul Cheney:

- *First of all, there's no doubt in my mind as I've seen it in clinical practice that this drug [Ampligen] is bioactive in this syndrome [CFS]...*

\* \* \*

- *The other parallel issue for Ampligen is that it appears that the longer you take it, if you are responding to it, the better the outcome...*

Further, your website is directly linked to a web page containing anecdotal reports of CFS patients who participated in clinical trials. For example, on the "*Other CFS Links*" page on your website there is a link entitled, "*The 'Ampligen 511 Panel' Patients Speak About Their Experiences with Ampligen at the AACFS Conference.*"... These patient testimonials promote Ampligen as safe or effective prior to approval. The following statements are examples of patient testimonials:

- *... after 10 years of consistent abnormality, a return to normal ranges for the first time, with Ampligen being the only new variable in my life, clearly demonstrates the efficacy of this drug*
- *Unlike IV gamma globulin, Ampligen is not offering me only symptomatic relief. I am healing from the inside out.*
- *There has been a dramatic improvement in my quality of life*

- *Call me Lazarus...the only reason I am here and functioning pretty well today is Ampligen. I have absolutely no doubts about its efficacy in the treatment of my illness*
- *No Adverse Effects—And Immediate Benefits to Boot-The Ampligen Bounce*

\* \* \*

#### **REQUESTED ACTIONS**

Hemispherx should immediately cease dissemination of materials or activities that contain these and similar claims, representations, and conclusions concerning the safety or effectiveness of Ampligen. In addition, Hemispherx should respond in writing no later than July 21, 2000 describing its plan to comply. Hemispherx should also include a list of materials being discontinued, as well as the date of discontinuation.

(Emphasis of italicized portions in original.)

115. Finally, the fact that the FDA was directly communicating with Defendant Carter in the above letters rather than a lower level employee, establishes Defendant Carter's hands-on participation in the FDA application process and control over the Company's communications with the agency.

#### **VIII. PLAINTIFFS' LOSS WAS PROXIMATELY CAUSED BY THE BELATED DISCLOSURE OF PREVIOUSLY MISREPRESENTED AND OMITTED MATERIAL FACTS**

116. The market for Hemispherx common stock was open, well-developed and efficient at all relevant times. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and course of conduct that artificially inflated the price of Hemispherx common stock and operated as a fraud or deceit on Class Period purchasers of Hemispherx shares by failing to disclose that the FDA delays were due to deficiencies in the NDA that Defendants had to address before the FDA would take any action on the NDA, and if the FDA was not satisfied, the review of the NDA would be further delayed or the NDA would not be approved. Instead, Defendants misleadingly told investors that the FDA delays were due to administrative issues and the FDA was not awaiting any information from the Company.

Further, during the Class Period, Defendants concealed that the NDA failed to include certain required studies because the Company had requested a waiver.

117. As a result of Defendants' materially false and misleading statements and material omissions as alleged herein, Hemispherx common stock traded at artificially inflated prices during the Class Period, reaching as high as \$3.75 per share on June 4, 2009.

118. Lead Plaintiff and the Class purchased or otherwise acquired Hemispherx common stock relying upon market information relating to Hemispherx and the integrity of the market price of Hemispherx common stock, thus causing economic loss and the damages complained of herein when the truth and/or the effects thereof were revealed and the artificial inflation was removed from the price of Hemispherx common stock.

119. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Lead Plaintiff and the Class.

120. But for Defendants' misrepresentations and omissions, Lead Plaintiff and the other members of the Class would not have purchased Hemispherx common stock at the artificially inflated prices at which they were purchased.

121. On November 2, 2009, before trading commenced for the day, the Company issued a press release entitled "Hemispherx Biopharma Updates Chronic Fatigue Syndrome (CFS); Treatment and Commercial Application Programs; Targets Completion of All NDA Regulatory Responses and Initiation of Expanded Clinical Collaborations in CFS," in which the Company first revealed that before the FDA will take any action on the NDA, the Company was first required to provide the FDA with additional reports on various subjects and the Company did not expect to finish providing the requested information until December 2009. Further, the Company revealed that at the time of the announced FDA delay in May 2009, several

outstanding NDA items required the Company's response, which is completely contrary to Defendants' statements made during the Class Period that the FDA was not awaiting any information from the Company.

122. As a direct result of the November 2, 2009 disclosure, the price of Hemispherx common stock plummeted from \$1.45 per share on October 30, 2009, to close at \$1.33 per share on November 2, 2009 (an 8.28% decline) on unusually heavy volume of 2,409,294 shares traded; and to decline further on November 3, 2009, when it closed at \$1.13 per share (a 15.04% decline), on unusually heavy volume of 8,739,506 shares traded. Over the two day period following the November 2, 2009 disclosure, the price of Hemispherx common stock fell a total of 22.07%. These decreases were the result of Defendants' disclosure of facts that had previously been concealed and caused the price of the Company's common stock to be artificially inflated, and this price decrease cannot be attributed either to general market or industry-wide events.

123. Indeed, in contrast to the sharp decline in the price of Hemispherx common stock on November 2 and 3, 2009, both the AMEX Biotech Stock Index ("BTK") and the NASDAQ Biotech Stock Index ("NBI") actually increased in value on November 2, 2009 by 2.92% for BTK and by 0.52% for NBI, with even larger increases over the two day period ending on November 3, 2009 of 6.48% for BTK and 2.45% for NBI. Moreover, in its 2008 Form 10-K Hemispherx compared the performance of its stock prices to the performance of: (a) the Standard & Poor's 600 Small Cap Index ("SML"), and (b) an index of four comparable peer companies (Avi Biopharma, CytRx Corp., GenVec and Oxigenc). While the SML index fell an insignificant 0.13% on November 2, 2009, this index increased 1.12% over the two-day period ending on November 3, 2009. Similarly, while two of four peer group stocks experienced small

price declines on November 2, 2009, these declines were much smaller than Hemispherx's price decline, and this group of comparable stocks fell an average of 0.71% on November 2, 2009, but increased an average of 3.57% over the 2 day period ending on November 3, 2009.

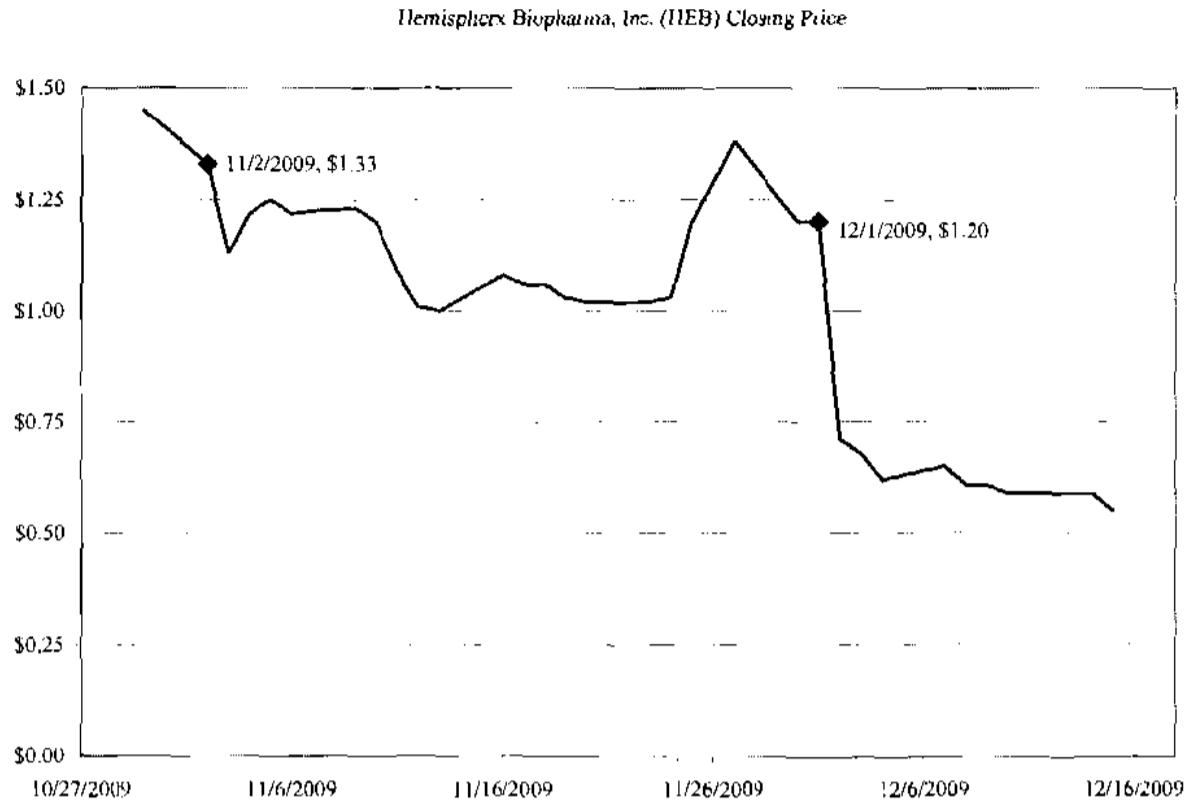
124. On December 1, 2009, after the markets closed, the Company issued a press release entitled, "Hemispherx Biopharma Receives Complete Response Letter from FDA on Ampligen New Drug Application for Chronic Fatigue Syndrome; Outlines Additional Recommendations," in which the Company disclosed that the FDA determined that it could not approve the Company's NDA application, most importantly because the Company did not provide credible evidence of efficacy of Ampligen. Indeed, the misrepresentation that the results of the Company's Phase III clinical trial for intent to treat analysis were statistically significant was a substantial cause of the decline in the stock price. The Company also disclosed that the FDA provided specific recommendations to the Company to address the outstanding issues, including completing at least one additional clinical study, submitting additional data, completing various analytical procedures, and resolving outstanding inspection issues. Finally, the Company disclosed that its requested waiver of completing certain required studies had been denied. The December 1, 2009 press release also disclosed that the Company had failed to satisfy FDA requirements to perform well-controlled testing for QT interval irregularities and that the new clinical trial would need to include such testing, which revealed that Defendant Strayer's Class Period representations about QT interval testing, as alleged herein, were materially false and misleading, which was also a substantial cause of the decline in the stock price.

125. As a direct result of the foregoing disclosures in the December 1, 2009 press release, the market price of Hemispherx common stock plunged an additional \$0.49 per share,

from a closing price of \$1.20 per share on December 1, 2009 to close at \$0.71 per share on December 2, 2009 (a 40.83% decline), on unusually heavy volume of 26,168,813 shares traded; and declined further on December 3, 2009, when it closed at \$0.68 per share (a 4.23% decline), on unusually heavy volume of 7,510,378 shares traded. Over the two day period following the December 1, 2009 disclosure, the price of Hemispherx common stock fell a total of 43.33%. This decrease was the result of Defendants' disclosure of facts that had previously been concealed and caused the price of the Company's common stock to be artificially inflated, and this price decrease cannot be attributed either to general market or industry-wide events.

126. Indeed, in contrast to the sharp decline in the price of Hemispherx common stock on December 2 and 3, 2009, both the BTK index and the NBI index actually increased in value on December 2, 2009 by 1.19% for BTK and by 0.89% for NBI, and over the two day period ending on December 3, 2009, the BTK increased by 0.83% and the NBI fell slightly by 0.13%. Similarly, the SML index increased by 1.12% on December 2, 2009 and declined an insignificant 0.27% over the two-day period ending on December 3, 2009. Moreover, while one of the common stocks of the four comparable peer companies identified by Hemispherx in its 2008 Form 10-K experienced a relatively much smaller price decline of under 1% on December 2, 2009, this group of comparable stocks increased an average of 5.44% on December 2, 2009, and also increased an average of 5.34% over the 2 day period ending on December 3, 2009.

127. As the chart below demonstrates, the market reacted swiftly and punishingly to the November 2, 2009 and December 1, 2009 disclosures, causing Lead Plaintiff and the Class to suffer economic harm:



128. As a result, members of the Class who purchased Hemispherx common stock during the Class Period and continued to hold those shares after the Class Period corrective disclosures, have sustained economic injury resulting from the decline(s) in the value of Hemispherx stock resulting from the revelations on November 2, 2009 and December 1, 2009. Members of the Class who purchased Hemispherx common stock during the Class Period, and sold those shares after the end of the Class Period, have suffered economic injury caused by Defendants' misrepresentations and/or omissions during the Class Period that did not fully come to light until December 1, 2009.

129. Thus, the damage suffered by Lead Plaintiff and other members of the Class was a direct and proximate result of Defendants' fraudulent scheme to artificially inflate the price of

Hemispherx common stock, the disclosures of which caused the subsequent significant declines in the value of Hemispherx common stock.

130. The foregoing allegations describe Lead Plaintiff's theory of damages, demonstrate that Lead Plaintiff's damages were caused by the scheme to defraud as alleged herein, and negate any inference that Lead Plaintiff's losses were the result of general market conditions or other factors wholly unrelated to the false and misleading information complained of herein.

**IX. APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET**

131. The presumption of reliance established by the fraud-on-the-market doctrine applies to this action.

132. At all relevant times, the market for Hemispherx common stock was efficient for the following reasons, among others:

- a. Hemispherx common stock met the requirements for listing, and was listed and actively traded on the NYSE Amex Equities, formerly known as the American Stock Exchange, a highly efficient and technologically advanced equities market;
- b. As a regulated issuer, Hemispherx filed periodic public reports with the SEC;
- c. Hemispherx regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

- d. According to the Company's Form 10-K filed with the SEC on March 16, 2009, as of March 3, 2009, there were 80,881,135 shares of Hemispherx common stock outstanding.
- e. Following the Company's three Class Period securities offerings, the number of outstanding shares increased. Specifically, according to the Company's Form 10-Q filed with the SEC on November 9, 2009, as of November 6, 2009, there were 132,724,202 shares of Hemispherx common stock outstanding;
- f. According to Bloomberg, during the Class Period, the average number of Hemispherx common shares held by the public was approximately 123.69 million;
- g. As of March 3, 2009, Hemispherx had approximately 233 shareholders of record;
- h. During the Class Period, Hemispherx common stock had a high average weekly trading volume of approximately 91.6 million shares;
- i. During the Class Period, Hemispherx was followed by numerous securities analysts employed by brokerage and securities research firms who regularly wrote reports that were distributed to certain customers of their respective brokerage and research firms. Each of these reports was publicly available and entered the public marketplace; and
- j. As demonstrated herein, there are "empirical facts" showing causation between corporate events or releases and an immediate response in the price of Hemispherx common stock.

133. As a result of the foregoing, the market for Heinispherx common stock promptly digested current information regarding Heinispherx from all publicly available sources and reflected such information in Heinispherx's stock prices.

134. Plaintiffs and all other members of the Class purchased shares of Heinispherx common stock at prices set by the market and did so in reliance on the integrity of those prices. Under these circumstances, all purchasers of Heinispherx common stock during the Class Period suffered similar injury through their purchase of Heinispherx common stock at artificially inflated prices, and thus, a presumption of reliance applies.

**X. INAPPLICABILITY OF THE SAFE HARBOR**

135. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint, because the specific statements pleaded herein were neither identified as "forward-looking statements" when made, nor accompanied by meaningful cautionary language identifying important factors that could cause actual results to differ materially from those in the specific statements. To the extent that the statutory safe harbor applies to any of the statements pleaded herein, Defendants are liable for those statements because at the time each of those forward-looking statements were made, the speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was made by or with the approval of an executive officer of the Company who knew that the statement was false or misleading when made.

**XI. CLASS ACTION ALLEGATIONS**

136. Lead Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased Heinispherx common

stock during the Class Period (the "Class"). Excluded from the Class are the Defendants, directors and officers of Hemispherx and their families and affiliates.

137. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Millions of shares of Hemispherx stock were traded each week during the Class Period by hundreds of persons.

138. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members, common questions include:

- a. Whether the Exchange Act was violated by Defendants;
- b. Whether Defendants omitted and/or misrepresented material facts;
- c. Whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;
- d. Whether Defendants knew or recklessly disregarded that their statements were false and misleading;
- e. Whether the prices of Hemispherx common stock were artificially inflated; and
- f. The extent of damage sustained by Class members and the appropriate measure of damages.

139. Lead Plaintiff's claims are typical of those of the Class because Lead Plaintiff and the Class sustained damages from Defendants' wrongful conduct.

140. Lead Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Lead Plaintiff has no interests which conflict with those of the Class.

141. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

**COUNT 1**

**(For Violation of §10(b) of the Exchange Act and Rule 10b-5 Against All Defendants)**

142. Lead Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

143. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

144. Defendants violated §10(b) of the Exchange Act and Rule 10b-5 in that they:

- a. Employed devices, schemes, and artifices to defraud;
- b. Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
- c. Engaged in acts, practices and a course of business that operated as a fraud or deceit upon Lead Plaintiff and others similarly situated in connection with their purchases of Hemispherx common stock during the Class Period.

145. Lead Plaintiff and the Class have suffered damages in that, in reliance of the integrity of the market, they paid artificially inflated prices for Hemispherx common stock. Lead Plaintiff and the Class would not have purchased Hemispherx common stock at the prices they

paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

146. As a direct and proximate result of these Defendants' wrongful conduct, Lead Plaintiff and the other members of the Class suffered damages in connection with their purchases of Hemispherx common stock during the Class Period.

**COUNT II**

**(For Violation of §20(a) of the Exchange Act Against All Defendants)**

147. Lead Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

148. Defendants Carter and Strayer acted as control persons of Hemispherx within the meaning of §20 of the Exchange Act. By virtue of their positions and power to control public statements about Hemispherx, Defendants Carter and Strayer had the power and ability to control the actions of Hemispherx and its employees. Hemispherx controlled Defendants Carter and Strayer and its other officers and employees. By reason of such conduct, Defendants are liable pursuant to §20(a) of the Exchange Act.

**PRAYER FOR RELIEF**

WHEREFORE, Lead Plaintiff prays for judgment as follows:

- a. Determining that this action is a proper class action and certifying Lead Plaintiff as class representative under Rule 23 of the Federal Rules of Civil Procedure;
- b. Awarding compensatory damages in favor of Lead Plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- c. Awarding Lead Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

d. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

**JURY DEMAND**

Lead Plaintiff demands a trial by jury.

DATED: February 26, 2010

BERGER & MONTAGUE, P.C.

By

*Sherrie R. Savett*

Sherrie R. Savett (PA Bar No. 17646)  
Carole A. Broderick (PA Bar No. 12001)  
Barbara A. Podell (PA Bar No. 28583)  
Eric Lechtzin (PA Bar No. 62096)  
1622 Locust Street  
Philadelphia, PA 19103  
Tel.: (215) 875-3000  
Fax: (215) 875-4604

Charles J. Piven  
Yelena Trepentin  
BROWER PIVEN  
A Professional Corporation  
1925 Old Valley Road  
Stevenson, Maryland 21153  
(410) 332-0030

and

David A.P. Brower  
BROWER PIVEN  
A Professional Corporation  
488 Madison Avenue, 8th Floor  
New York, NY 10021  
Telephone: (212) 501-9000  
Facsimile: (212) 501-0300

Counsel for Lead Plaintiff Hemispherx  
Investor Group and the Proposed Class

malta51K587